

Research and Development SOP009 - Roles and Responsibilities Standard Operating Procedure

V2.0

March 2026

Table of Contents

1. Introduction	4
1.9. Scope	5
1.10. Definitions / Glossary	5
2. Purpose of this Standard Operating Procedure	7
3. Ownership and Responsibilities	7
3.1. Role of the Sponsor	7
3.2. Role of the Chief Investigator (CI) for Hosted Studies	9
3.3. Role of the Chief Investigator (CI) for Sponsored Studies	11
3.4. Role of the Principal Investigator (PI)	12
3.5. Role of the Sub-investigator (Sub-I)	14
3.6. Role of the Clinical Research Team	14
4. Standards and Practice	15
4.1. Pre-study phase	15
4.2. Open study phase	15
4.3. Study Closure Phase	16
4.4. Post-Study Closure Phase	16
4.5. Absence of Chief or Principal Investigator	16
5. Dissemination and Implementation	17
5.11. Training and Education	17
5.12. SOP Deviations	18
6. Monitoring compliance and effectiveness	18
7. Updating and Review	19
8. Equality and Diversity	19
Appendix 1. Governance Information	20
Appendix 2. Quality and Equality Impact Assessment (QEIA) Guidance Form	24

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”) 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/uksi/2025/538/regulation/37>
- 1.2. International Conference on Harmonisation Good Clinical Practice (ICH GCP) E6 (R3) outlines specific responsibilities for various functions involved in clinical trials, including investigators, sponsors, and ethics committees, to ensure the integrity and quality of clinical research. ICH GCP E6 (R3) (II) Principle 10 states; “Roles and responsibilities in clinical trials should be clear and documented appropriately”.
https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuide_line_2025_0106.pdf
- 1.3. Section 9 of the UK Policy Framework for Health and Social Care Research (2017) outlines the roles and responsibilities of the various stakeholders involved in health and social care research. [UK Policy Framework for Health and Social Care Research - Health Research Authority](#)
- 1.4. 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”) Regulation 2 in Section 3(2)(u) defines the investigator as: “the health care professional who is responsible for the conduct of that trial at that trial location or, if more than one, the trial locations; and who is, if the trial is conducted by a team of health care professionals at that location or locations, the leader responsible for that team”.
<https://www.legislation.gov.uk/uksi/2025/538/regulation/3>
- 1.5. The Medicines in Human use (Clinical Trials) (Amendment) Regulations 2025 (referred to as the “amended Clinical Trials Regulations”), Part 2, Section 5, Insertion of new regulation 3B “The investigator, in relation to a clinical trial, shall be a health care professional who is appropriately trained to undertake that role in a clinical trial.” <https://www.legislation.gov.uk/uksi/2025/538/regulation/5>
- 1.6. International Conference on Harmonisation Good Clinical Practice (ICH GCP) E6 (R3) Section 2 outlines specific responsibilities for investigators, to ensure the integrity and quality of clinical research.
https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuide_line_2025_0106.pdf
- 1.7. This document sets out roles and responsibilities for the conduct and management of clinical trials and research studies for Royal Cornwall Hospitals NHS Trust (RCHT). It aims to provide clear guidance on the conduct of clinical trials and research studies to ensure compliance with relevant regulatory requirements, Good Clinical Practice (GCP) standards and Trust policies.

1.8. This version supersedes any previous versions of this document.

1.9. Scope

- 1.9.1. This document details the roles and responsibilities of the sponsor, chief investigator, principal investigator and other research staff, as described in Good Clinical Practice (GCP).
- 1.9.2. This SOP applies to all personnel that are conducting research for RCHT including: staff that are full or part-time employees of the Trust, those working at the Trust with employment contracts funded partially or wholly by third parties, those working at the Trust under an honorary contract or under the remit of a valid research passport, those seconded to and providing consultancy to the Trust, and to students undertaking training and educational projects at the Trust.

1.10. Definitions / Glossary

- 1.10.1. **Good Clinical Practice (GCP)** is an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.
- 1.10.2. **Clinical Trial of Investigational Medicinal Product (CTIMP)** is any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effect of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal products(s) and/or study absorption, distribution, metabolism and excretion of one or more investigational product(s) with the object of ascertaining its (their) safety and/or efficacy.
- 1.10.3. **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.
- 1.10.4. **Research Ethics Committee (REC)** is a group of people appointed to review research proposals to assess formally if 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.
- 1.10.5. **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.

- 1.10.6. **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.

- 1.10.7. **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).
- 1.10.8. **Associate PI** is a healthcare professional who does not have research as a core part of their role, who is given the opportunity to experience what it means to work and deliver a NIHR portfolio study under the mentorship of a local PI.
- 1.10.9. **Sub-investigator (Sub-I)** is any individual member of the clinical study team suitably designated by the investigator at a study site to perform critical study-related procedures and/or to make important study-related decisions (e.g., associates, residents, research fellows).
- 1.10.10. **The Research Team** is a group of people involved in the conduct of a research project at site. It may include care professionals, academics, patients and service users, members of the public, research professionals, students and/or scientists.

1.10.11. **Acronyms**

- **CI:** Chief Investigator.
- **CTIMP:** Clinical Trial of an Investigational Medicinal Product.
- **GCP:** Good Clinical Practice.
- **HRA:** Health Research Authority.
- **ICH GCP:** International Council for Harmonisation of Good Clinical Practice.
- **MHRA:** Medicines and Healthcare products Regulatory Agency.
- **PI:** Principal Investigator.
- **PPIE:** Patient and Public Involvement and Engagement.
- **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 document defines roles and responsibilities for the conduct of clinical trials and research studies for Royal Cornwall Hospitals NHS Trust (RCHT).
- 2.2. The purpose of this standard operating procedure (SOP) is to ensure that all research staff understand the key roles and responsibilities for the effective management and conduct of clinical trials and research studies, in line with the regulatory requirements, Good Clinical Practice (GCP) standards, relevant protocol and sponsor expectations.

3. Ownership and Responsibilities

3.1. Role of the Sponsor

The sponsor is the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. The Sponsor is responsible for:

- Proportionate approaches to risk management, to ensure the rights, safety and well-being of the participants and the reliability throughout the clinical trial or research study life cycle.
- Incorporating quality into the design for clinical trials by identifying factors that are critical to the quality of the trials and managing risks of those factors.
- Ensuring that all aspects of the clinical trial or research study are operationally feasible and should avoid unnecessary complexity, procedures and data collection.
- Ensuring that the clinical trial or research study is scientifically sound, described in a clear and detailed protocol, and allows identification of all the data reported for each participant.
- Selecting the site(s) and investigator(s) to carry out the study, ensuring the investigators, research teams and research sites are suitable and that there are sufficient resources available to complete the study at the specified sites.
- Providing the investigator(s) with the necessary information to conduct the clinical trial or research study, ensuring that they are suitably qualified, experienced and trained.
- Where a PI is not medically qualified, ensuring appropriate medical support is in place for oversight and medical decision making for a clinical trial. This is usually a qualified physician but can be a qualified dentist or other suitably qualified healthcare professional, depending on the type of research being done.

- Ensuring that roles and responsibilities of the parties involved in the research are agreed and documented.
- Ensuring adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project.
- Ensuring the necessary research approvals are obtained from; Research Ethics Committee (REC), Health Research Authority (HRA) and Medicines and Healthcare products Regulatory Agency (MHRA) for Clinical Trials of Investigational Medicinal Products (CTIMPs).
- Verifying that regulatory and practical arrangements are in place, before permitting the research to begin in a safe and timely manner.
- Putting and keeping in place arrangements for adequate finance and management of the research project.
- Ensuring that research proposals and protocols consider systematic reviews of relevant existing research evidence and other relevant research in progress.
- Preparing and submitting clinical trial or research study applications and modifications to the appropriate regulatory agencies.
- Ensuring that any relevant reviewing ethics committees and regulatory agencies are promptly informed of any significant new information in a clinical trial or research study, including important findings that affect patient and product safety.
- Ensuring compliance with labelling, reporting and record keeping requirements.
- Ensuring that the clinical trial or research study is conducted in accordance with Good Clinical Practice (GCP) standards.
- Ensuring that effective procedures and arrangements are kept in place and adhered to for reporting (e.g., progress reports, safety reports) and for monitoring the research, including its conduct and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments.
- Evaluating the safety of the investigational product(s) in clinical trials by implementing or enforcing clinical trial modifications and the management and reporting of adverse events.
- Ensuring appropriate arrangements for making information about the research publicly available before it starts (unless a deferral is agreed by or on behalf of the REC).
- Agreeing appropriate arrangements for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after the trial or study has finished.

- Ensuring arrangements for information about the findings of the research are made available, including, where appropriate, to participants (for educational research, registration, accessibility of data and tissues, and dissemination may be limited to institutional arrangements).
- Ensuring that the REC and MHRA for clinical trials involving CTIMPs, are notified when the study has ended.

3.2. **Role of the Chief Investigator (CI) for Hosted Studies**

The UK Policy Framework for Health and Social Care Research Section 9.2 define the responsibilities of the chief investigator. The chief investigator is the overall lead researcher for a research project. In addition to their responsibilities if they are members of a research team, chief investigators are responsible for the overall conduct of a research project. [UK Policy Framework for Health and Social Care Research - Health Research Authority](#)

The responsibilities of the Chief Investigator (CI) may vary dependent upon whether the clinical trial or research study is hosted or sponsored. The CI for may also be the Principal Investigator (PI) for the research hosted by Royal Cornwall Hospitals NHS Trust (RCHT).

The CI as defined by the Clinical Trials Regulations (SI 2004/1031) and the Amended Clinical Trials Regulations (SI 2025/538), as the healthcare professional who takes primary responsibility for the conduct of the trial.

CIs may delegate tasks to appropriately trained and qualified members of their research team; however, they must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibilities.

The CI for clinical trials or research studies hosted by RCHT is responsible for:

- Being aware of and agreeing to all roles and responsibilities delegated to them by the sponsor prior to the commencement of the research.
- Understanding and applying the legal and ethical requirements in research and adhering to the appropriate standard operating procedures and policies relating to research.
- Ensuring that the study is planned, set-up, conducted, documented, and reported according to the appropriate regulatory requirements, protocol, Good Clinical Practice (GCP) and relevant SOPs.
- Ensuring that the information provided to potential participants is in a suitable format that is clear and relevant to their participation in the research and, where consent is required, to their decision-making about taking part in the research.
- Adhering to the agreed arrangements for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after the research has finished (sponsors, funders or others may set expectations about making data and tissue available).

- Ensuring that everyone involved in the conduct of the research is qualified by education, training and experience, to perform their respective delegated task(s). Training should be proportionate to the activities undertaken by the staff involved in the clinical trial or research study. The training should be appropriate and tailored to the needs and risks of the associated research.
- Adhering to the agreed procedures and arrangements for reporting (e.g., progress reports, safety reports) and for monitoring the research, including its conduct, the participants' safety and well-being, and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments.
- Supporting in the assessment of all SAEs, serious adverse reactions (SARs) and suspected unexpected serious adverse reactions (SUSARs).
- Implementing Urgent Safety Measures (USMs) when an unexpected event poses a serious risk to participants. Support the sponsor with notifying the relevant authorities, such as the Medicines and Healthcare products Regulatory Authority (MHRA).
- Ensuring the sponsor is provided with details of all AEs identified in the protocol as critical to the evaluation of safety within the agreed timeframes specified in the protocol.
- Supporting the sponsor to ensure the Trial Master File (TMF) is maintained and kept inspection ready.
- Maintaining regular communication with the sponsor and being involved in decision-making and correspondence related to the clinical trial or research study.
- Ensuring that all data and documentation relating to the clinical trial or research study are available at the request of the inspection and regulatory authorities. The sponsor must be kept informed of the location of all archived data and the contact details of the person responsible.
- Supporting the submission of annual written summaries of the trial status to the sponsor, Trust R and D Office, NHS Ethics Committee and the Competent Authority and provide a summary outcome at the end of the trial. This includes annual and end of trial safety reporting.
- Gaining assurance that there are appropriate arrangements in place to archive the TMF/Investigator Site File (ISF) and anonymised data when the research has finished, and to ensure it is still accessible when required.
- The responsibilities outlined in [Section 3.4](#), if also acting as the Principal Investigator for the site.

3.3. Role of the Chief Investigator (CI) for Sponsored Studies

The responsibilities of the Chief Investigator (CI) for studies sponsored by Royal Cornwall Hospitals NHS Trust (RCHT) will be the same as those outlined in [Section 3.2](#). In addition, the CI for sponsored studies will be responsible for:

- Designing research which is scientifically sound and aligns with RCHT research objectives. Ensuring the research proposal takes account of any systematic reviews, other research evidence and research which is currently in progress.
- Ensuring the design of the research makes effective use of patient and public involvement and engagement (PPIE) in line with the UK Standards for Public Involvement. <https://sites.google.com/nihr.ac.uk/pi-standards/standards>
- Ensuring that the research proposal or protocol has been submitted for appropriate independent expert (peer) review (for educational research, the CI will be a supervisor who may provide an appropriate level of review) and revised in line with the outcomes of the review.
- Ensuring authorisation is obtained from the appropriate RCHT Care Division(s) for the trial or study to take place.
- Ensuring the clinical trial or research study has appropriate Research Ethics Committee (REC) approval, Medicines and Health Care Products Regulatory Agency (MHRA) approval if appropriate, and all other applicable regulatory approvals in place prior to commencement.
- Ensuring that capacity and capability confirmation are obtained from host sites (where applicable) when the full approvals, contracts and financial agreements are in place.
- Ensuring R and D as the sponsor, and necessary REC, MHRA and competent authority approvals are gained for all protocol modifications. The CI will ensure that the changes are implemented across all sites for the trial or study.
- Implementing Urgent Safety Measures (USMs) when an unexpected event poses a serious risk to participants.
- Ensuring that all adverse events and reactions which were recorded during the clinical trial or research study are subject to a statistical analysis; and that any subsequent conclusions are included in the trial or study's final report.
- Register trial in public database before first participant recruited or 90 days after approval (whichever is soonest).
- Adhering to the agreed arrangements for making information about the research publicly available before it starts (unless a deferral is agreed by or on behalf of the research ethics committee).
- Disseminating the findings from the clinical trial or research study promptly and providing feedback as appropriate to participants.

- The responsibilities outlined in [Section 3.4](#), if also acting as the Principal Investigator for the site.

3.4. Role of the Principal Investigator (PI)

The Principal Investigator (PI) is responsible for the local site in a study and may also be the Chief Investigator for the study. PIs may delegate tasks to appropriately trained and qualified members of their research team; however, they must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibilities.

Under the Clinical Trials Regulations Amendment 2025 (SI 2025/538), investigators may come from a broader range of professions, however, they must be registered with an appropriate UK statutory regulator.

The PI is responsible for:

- Ensuring participant safety, data integrity, and compliance with Good Clinical Practice (GCP), regulatory requirements and the approved protocol.
- Understanding the legal and ethical requirements in research and are familiar with the appropriate standard operating procedures and policies relating to research.
- The medical care and supervision of participants on clinical trials or research studies. Where a PI is not medically qualified, ensuring appropriate medical support must be in place for oversight and medical decision making for a clinical trial. This is usually a qualified physician but can be a qualified dentist or other suitably qualified healthcare professional, depending on the type of research being done.
- Ensuring the research is conducted to the standards as set out in the UK Policy Framework for Health and Social Care Research.
- Ensuring all research staff carrying out trial and study activities are appropriately qualified, experienced, and adequately informed about the protocol and of their trial or study related duties and responsibilities.
- Ensuring each member of the research team, who has direct involvement with participants and/or identifiable data, has a contract of employment with the organisation, honorary contract or research passport.
- Ensuring delegated roles and responsibilities are appropriately recorded within the delegation log held in the Investigator Site File (ISF) for each clinical trial and research study. The PI can delegate duties, but never the responsibility for the study at the site. Refer to SOP R and D SOP030 Delegation of Research Duties (see Documents folder in EDGE).

- Acknowledging their supervisory role of delegated study staff, ensuring that they are observing the study protocol requirements and adhering to their individual roles and responsibilities, as defined on the delegation log for the trial or study.
- Ensuring all research staff involved in Clinical Trial of Investigational Medicinal Product (CTIMP) studies are aware of their legal responsibilities.
- Ensuring students and new researchers are adequately trained, supervised and supported.
- Ensuring the study does not start without the relevant approvals from the MHRA (as appropriate), HRA, REC, R and D capacity and capability confirmation and sponsor's Green Light (authorisation to begin recruitment).
- Ensuring the research team acts on any conditions attached to the ethics opinion.
- Ensuring research follows the protocol or proposal agreed by the relevant ethics committee, R and D function and by the sponsor, unless urgent safety measures are necessary.
- Ensuring all eligibility assessments are met and participants consented, recruited and followed up appropriately.
- Having oversight of the Investigator Site File (ISF) and ensuring it is always maintained and kept inspection ready.
- Ensuring procedures are in place for the collection of high-quality, accurate data and that the data is processed in accordance with the Data Protection Act 2018 and the Caldicott Principles.
- Ensuring all protocol modifications are reviewed and approved by the relevant review bodies, this includes the HRA, REC and MHRA, as appropriate.
- When applicable, the participant's GP is informed of their participation in a clinical trial or research study.
- Safety reporting including reporting Serious Adverse Events (SAEs), Serious Adverse Reactions (SARs) and Suspected Unexpected Serious Adverse Reactions (SUSARs) are communicated to the CI, sponsor and R and D as required. Refer to R and D SOP035 Recording, Managing and Reporting Adverse Events (see Documents folder in EDGE).
- Reviewing and acknowledging sponsor reported safety information and other relevant changes, as and when a safety incident occurs.

- Holding regular meetings or communicating with the research team to ensure oversight of the research and to disseminate sponsor reported safety information and other relevant changes and updates.
- Ensuring that participant feedback is handled with respect, confidentiality and that any necessary actions are taken to address concerns and complaints.
- Disseminating research findings following publication, communicating effectively and in a timely manner to participants, as appropriate.
- Ensuring appropriate arrangements are in place to archive the data when the research has finished, and to ensure it remains accessible.
- Ensuring all data and documentation relating to the clinical trial or research study are available at the request of the inspection and auditing authorities.
- Being available for monitor meetings and ensure sponsor feedback is acted upon promptly, as appropriate.
- Having oversight of the study closure requirements in line with the R and D SOP043 Closure Process for Hosted Studies (see Documents folder in EDGE).

3.5. Role of the Sub-investigator (Sub-I)

The Sub-investigator (Sub-I) is responsible for:

- Undertaking part or all the PI's activities for a research study, as determined by the sponsor, protocol, and as delegated by the PI.
- Ensuring that they are adequately trained and familiar with the protocol, informed of any changes in the protocol and provided with safety information including the Investigators Brochure (IB) and all safety updates.

3.6. Role of the Clinical Research Team

The clinical research team is responsible for:

- Ensuring participant safety, data integrity and compliance with Good Clinical Practice (GCP), regulatory requirements and the approved protocol.
- Understanding the legal and ethical requirements in research and are familiar with the appropriate standard operating procedures and policies relating to research.
- Conducting the research according to the approved research protocol, and any complementary information (such as the REC application form or investigator brochure), in compliance with any applicable regulatory standards and guidance.

- Adhering to their individual roles and responsibilities, as defined on the delegation log for the clinical trial or research study.
- Completing appropriate training, the extent of which will depend on the activities being undertaken, ensuring that they have the knowledge and skills required to carry out the allocated tasks.
- Signing the study delegation log and ensuring that the PI has countersigned prior to undertaking any activities on the study, to confirm that they have been delegated these tasks appropriately.
- Ensuring that potential research participants are provided with the information and relevant documentation they need to help them decide whether they wish to take part in research or not, and that they are given reasonable time to reach their decision. Refer to R and D SOP029 Informed Consent (see Documents folder in EDGE).

4. Standards and Practice

4.1. Pre-study phase

- 4.1.1. The conduct of clinical trials and research studies is the responsibility of the sponsor, the CI and the PI at the participating site. The sponsor, CI and PI may delegate some of their duties, but the responsibility for ensuring these duties are carried out remains with them.
- 4.1.2. During the pre-study phase of the clinical trial or research study, the PI and delegated research team should discuss and agree on the clinical trial or research study requirements with the sponsor or sponsor representative as appropriate, ensuring all necessary procedures and assessments are understood and clearly defined.
- 4.1.3. All protocol requirements will be identified and delegation of responsibilities agreed prior to commencing recruitment of participants.
- 4.1.4. The PI should review each staff member's tasks and responsibilities and countersign the delegation log as confirmation that the PI is delegating the listed tasks to that research team member. The PI's countersignature should be completed prior to a staff member commencing any trial or study related activities. Refer to R and D SOP030 Delegation of Duties (available in the Documents folder in EDGE).

4.2. Open study phase

- 4.2.1. The PI and delegated study staff responsible for the clinical trial or research study must ensure they are observing the study protocol requirements and adhering to their individual roles and responsibilities, as in the delegation log for the trial or study.

- 4.2.2. Any new study team staff members working on the trial are responsible for signing the delegation log with PI countersignature prior to working on the trial or study, to confirm that they have been delegated these tasks appropriately. Refer to R and D SOP030 Delegation of Duties (available in the Documents folder in EDGE).

4.3. Study Closure Phase

- 4.3.1. The PI has overall responsibility for the clinical trial or research study during the closure phase, at the site.
- 4.3.2. The PI and delegated research staff should ensure that the closure of the clinical trial or research study adheres to the requirements of the relevant protocol and the procedures outlined in SOP043 Closure Process for Hosted Studies (available in the Documents folder in EDGE).

4.4. Post-Study Closure Phase

- 4.4.1. During the closure phase of a clinical trial or research study, the PI has overall responsibility for the trial or study at site.
- 4.4.2. During the closure phase, the PI and delegated research staff responsible for the clinical trial or research study should ensure they are following the protocol, the sponsor's closedown procedures, R and D SOP043 Closure Process for Hosted Studies and R and D SOP044 Archiving Essential Documents (see Documents folder in EDGE). Research staff should adhere to their individual responsibilities, as defined in the delegation log (refer to R and D SOP030 Delegation of Duties, see Documents folder in EDGE).

4.5. Absence of Chief or Principal Investigator

- 4.5.1. In some cases, it may be necessary to appoint an acting or new CI or PI where the absence is likely to be significant.
- 4.5.2. For planned absences, the CI or PI is responsible for arranging adequate cover, ensuring an investigator is delegated to the role, trained in the study and the delegation and training log updated appropriately. Ensure the sponsor is informed, as appropriate.
- 4.5.3. For unplanned absences of the CI or PI, the research sponsor together with the site (if the absence is for the PI at the host site) will be responsible for ensuring that appropriate arrangements are made for the continued conduct of the study. Ensure that sponsor is informed, as appropriate.
- 4.5.4. As determined by the sponsor, the HRA should be notified about cover arrangements for absent CIs. For PIs, the sponsor and the Trust's R and D function must be notified about cover arrangements for absent PIs.
- 4.5.5. If the regulatory bodies have any concerns about the suitability of the arrangements, they should notify the sponsor. They have the discretion to request the formal appointment of an acting CI or PI.

- 4.5.6. Work Instruction WI28 Absence of CI and/or PI (see Documents folder in EDGE) details the process to be followed in the absence of the CI and/or PI.

5. Dissemination and Implementation

- 5.1. Trust-wide Research and Development (R and D) procedural documents will be stored on the Trust's Document Library, and a working copy will be accessible through EDGE providing alternative access for research staff.
- 5.2. The Research Governance Manager or delegate will arrange for documents to be published on the Trust Documents Library and EDGE.
- 5.3. The Research Governance Manager or delegate will ensure that any previous versions of the document are made inaccessible to general EDGE users, in accordance with the EDGE document archiving procedure.
- 5.4. 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 or WI.
- 5.5. 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 AD19 Training Matrix (see Documents folder in EDGE).
- 5.6. Details of how to access EDGE is available by contacting the Research Systems Officer via rch-tr.edge@nhs.net.
- 5.7. 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 endeavor to notify research staff of any SOP developments that may be relevant to them via staff communications, for example, 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.
- 5.8. Consideration must be given at study set up as to which SOPs will not apply to a specific study, with agreement from the R and D Senior Management Team (SMT). Full details must be included as a written statement in the study site file.
- 5.9. Whilst SOPs may be printed, the electronic version maintained on R and D internet page is the controlled copy. Any printed copies are not controlled documents.
- 5.10. Chief and Principal Investigators will be notified as per the Trust's process for notifying all staff of new procedural documents.
- 5.11. **Training and Education**
 - 5.11.1. When a new SOP is authorised, or when an existing SOP is revised, self-directed training as specified and detailed by the SMT must be carried out by all staff to which the SOP is relevant, and this training documented in their training record.

5.11.2. 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.

5.12. SOP Deviations

5.12.1. 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.

5.12.2. 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 6.16 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 Trust's [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 SOP009 - Roles and Responsibilities Standard Operating Procedure V2.0
This document replaces (exact title of previous version):	Research and Development SOP009 - Roles and Responsibilities Policy and Procedure V1.1
Date Issued/Approved:	February 2026
Date Valid From:	March 2026
Date Valid To:	March 2029
Directorate / Department responsible (author/owner):	Caroline Phillips, Research Governance Manager.
Contact details:	rcht.researchqualityassurance@nhs.net
Brief summary of contents:	Defines the roles and responsibilities for research staff, providing clear guidance on the conduct of Research Studies and Clinical Trials, aligned to the UK Policy Framework for Health and Social Care Research - Health Research Authority
Suggested Keywords:	Standard Operating Procedures (SOP). Good Clinical Practice (GCP). Research and Development (R and D).
Target Audience:	RCHT: Yes CFT: No CIOB ICB: No
Executive Director responsible for Policy:	Chief Strategy Officer.
Approval route for consultation and ratification:	Research and Development Senior Management Team (SMT)
General Manager confirming approval processes:	Bianca Mills, Head of Research and Development
Name of Governance Lead confirming approval by specialty and care group management meetings:	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:	The Medicines for Human Use (Clinical Trials) Regulations 2004 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/ The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 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/ International Council for Harmonisation (ICH) Guideline for Good Clinical Practice E6 (R3), (06 January 2025). https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf 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/ Data Protection Act 2018 https://www.legislation.gov.uk/ukpga/2018/12/contents The Caldicott Principles https://www.gov.uk/government/publications/the-caldicott-principles R and D SOP001 Preparation, Approval and Review of SOPs/WIs. R and D SOP029 Informed Consent. R and D SOP030 Delegation of Research Duties. R and D SOP035 Recording, Managing and Reporting Adverse Events. R and D SOP043 Closure Process for Hosted Studies. R and D SOP044 Archiving Essential Documents. R and D AD07 Glossary of Terms.

Information Category	Detailed Information
	R and D AD19 Training Matrix. R and D WI28 Absence of CI and/or PI.
Training Need Identified?	Yes – details provided in Section 5
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Research and Innovation

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
02/03/2023	1.0	New Standard Operating Procedure (SOP) for Roles and Responsibilities. Requirement for the SOP has been identified through the findings in monitoring visits and audits.	Caroline Phillips, Research Governance Manager
16.06.2023	V1.1	Title updated to reflect the document is a Standard Operating procedure (SOP). Section fore Scope and Definition moved to under Section 1 – to align with SOP Template.	Caroline Phillips, Research Governance Manager
19/02/2026	V2.0	Review to reflect the changes to the clinical trials regulations and ICH GCP guidance. 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. R and D SOP009 - Roles and Responsibilities combined with R and D SOP010 Investigators Responsibilities.	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 six 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. Quality and Equality Impact Assessment (QEIA) Guidance Form

The QEIA process allows RCHT to monitor the impact of changes to its policies and services, ensuring that nobody is unduly disadvantaged.

For guidance, please contact the Equality, Diversity and Inclusion Team at rcht.inclusion@nhs.net

1. About the Policy / Service Change:

Information Category	Detailed Information
Individual completing QEIA: (Name, Role, Email)	Caroline Phillips, Research Governance Manager. rcht.researchqualityassurance@nhs.net
Service Area: (Department, Care Group)	Research and Development. Corporate.
Name of document:	Research and Development SOP009 Roles and Responsibilities V2.0.
Type of document: (Policy, Strategy, Service Change)	Standard Operating Procedure (SOP).
Policy / Service Change Objective(s): (What should it achieve, and for whom?)	Defines the roles and responsibilities for research staff, providing clear guidance on the conduct of Research Studies and Clinical Trials, aligned to the HRA Framework for Health and Social Care Research
Does this Policy / Service Change: (Select all that apply)	Eliminate Discrimination? Yes Advance Equal Opportunity? Yes Foster Good Relations? Yes
Which Groups are impacted by this policy? (Select all that apply)	Yes – Workforce. No – Patients. No – Visitors. No - System Partners. No - External Organisations. No – Contractors.

2. About the impact:

For each characteristic, please indicate whether you think the impact will be positive, negative or unknown, and provide a brief explanation:

Note: Stating 'This document has no impact on this group' for all characteristics will result in the document not being approved.

Characteristic	Impact	Explanation
Age	Positive	Procedural document for all staff members.
Sex	Positive	Procedural document for all staff members.
Gender Reassignment	Positive	Procedural document for all staff members.
Race, Ethnicity, Culture	Positive	Procedural document for all staff members.
Disability or Long-term Health Condition	Positive	Procedural document for all staff members.
Religion or Belief	Positive	Procedural document for all staff members.
Marriage and Civil Partnership	Positive	Procedural document for all staff members.
Pregnancy and Maternity	Positive	Procedural document for all staff members.
Sexual Orientation	Positive	Procedural document for all staff members.
Armed Forces Community	Positive	Procedural document for all staff members.
Low Income Households	Positive	Procedural document for all staff members.

A consultation must take place with appropriate groups to clarify unknown impacts and recommend mitigation of negative impacts.

3. About the Consultation

Information Category	Detailed Information
Which bodies have been consulted? (Not all will be required)	Yes Service Employees. No Employee Network Groups. No Union Representatives. No EDI Team. No Patient / Service Users. No Patient Advisory Group. No Patient Representatives. No Local / National Charities. No System Partners.

Information Category	Detailed Information
	No External Organisations. No Other.

Information Category	Detailed Information
Please list the individuals / groups who have been consulted: (Role, Organisation, Email. Avoid using individual names)	Senior Management Team (SMT) consulted during the development of this SOP.
Consultation Outcomes: (Positive feedback, new negative impacts, recommendations)	Recommendations aligned to the key roles and responsibilities for the effective management and conduct of clinical trials and research studies, in line with the regulatory requirements, Good Clinical Practice (GCP) standards, relevant protocol and sponsor expectations.
What action will you now take?	Continue without Amendments
Provide Details:	Negative impacts not identified during the development of this SOP.
Do any negative impacts remain?	No
Explain rationale for proceeding with negative impacts:	Not applicable – negative impacts not identified during the development of this SOP.

I am confident that this QEIA is an honest reflection of my efforts to comply with the Public Sector Equality Duty, and that all appropriate, necessary actions have been taken to mitigate any negative impacts as far as practicable.

Name:	Caroline Phillips	Role:	Research Governance Manager.
-------	-------------------	-------	------------------------------