

Research and Development SOP004 Reporting and Managing Non- compliance and Serious Breaches

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

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

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

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

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1. Introduction

- 1.1. International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines E6 (R3) paragraph 3.12.1 states that 'Non-compliance with the protocol, SOPs [Standard Operating Procedures], GCP and/or applicable regulatory requirement(s) by an investigator/institution or by member(s) of the sponsor's staff should lead to appropriate and proportionate action by the sponsor to secure compliance.'
https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf
- 1.2. The UK Policy for Health and Social Care Research outlines the principles that apply to all health and social care research and Principle 15: Compliance, states that 'Sanctions for non-compliance with these principles may include appropriate and proportionate administrative, contractual or legal measures by funders, employers, relevant professional and statutory regulators, and other bodies.'
<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/>
- 1.3. It is the sponsor's responsibility to ensure that research is undertaken in compliance with the approved protocol and SOPs and in accordance with GCP and regulatory requirements.
- 1.4. ICH GCP E6 (R3) paragraph 3.9.3 states 'The sponsor should determine necessary trial-specific criteria for classifying protocol deviations as important. Important protocol deviations are a subset of protocol deviations that may significantly impact the completeness, accuracy and/or reliability of the trial data or that may significantly affect a participant's rights, safety or well-being.'
- 1.5. It is a requirement of the Medicines for Human Use (Clinical Trials) Regulations 2004 ("the Clinical Trials Regulations") Regulation 29A as amended by the Medicines in Human Use (Clinical Trials) (Amendment) Regulations 2025 (referred to as the "amended Clinical Trials Regulations") Section 19, that the sponsor of a clinical trial shall notify the licensing authority in writing of any serious breach of Good Clinical Practice (GCP) or the trial protocol within 7 days of becoming aware of that breach. In the UK this is the Medicines and Healthcare products Regulatory Agency (MHRA). In addition, all serious breaches for CTIMP or Non-CTIMP studies, must be notified to the appropriate Research Ethics Committee (REC). MHRA guidance for the notification of serious breaches of GCP or the trial protocol is available via:
https://assets.publishing.service.gov.uk/media/5f22f594e90e071a603d33f4/Guidance_for_the_Notification_of_Serious_Breaches_of_GCP_or_the_Trial_Protocol_Version_6_08_Jul_2020.pdf
- 1.6. The MHRA's Good clinical practice in clinical trials guidance defines the categories of non-compliance under the grading of inspection findings.
<https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials>

- 1.7. The Medicines for Human Use (Clinical Trials) Regulations 2004 (“the Clinical Trials Regulations”) Regulation 30 as amended by the Medicines in Human Use (Clinical Trials) (Amendment) Regulations 2025 (referred to as the “amended Clinical Trials Regulations”) Section 20, specifies that the Sponsor or Investigator may take appropriate urgent safety measures (USM) in order to protect the subjects of a clinical trial against any immediate hazard to their health or safety. This measure can be taken prior to seeking approval from competent authorities and ethics committees. However, for all studies, any USMs implemented must be reported to the Sponsor as soon as practicable.

1.8. Scope

- 1.8.1. This Standard Operating Procedure (SOP) applies to all clinical trials and studies, both sponsored and hosted, conducted at the Royal Cornwall Hospitals NHS Trust (RCHT).
- 1.8.2. This SOP applies to all staff involved in research activities being conducted at RCHT.
- 1.8.3. Where RCHT is acting as a host site only, reporting to the sponsor must be conducted in line with the sponsor’s SOPs; RCHT does not assume sponsor-level responsibilities.

1.9. Definitions and Glossary

- 1.9.1. **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.
- 1.9.2. **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.
- 1.9.3. **Deviation** is a departure from one or more of the protocol, Standard Operating Procedures (SOP), GCP or regulatory requirements that have been identified retrospectively, which is neither critical or major and so not likely to affect to a significant degree:
- The safety or physical or mental integrity of the trial participant. Or,
 - The scientific value of the trial.
- 1.9.4. **Violation** can occur when there is a departure from the expected conduct of the trial or study (approved trial protocol, trial documents, SOPs or GCP), which may result in harm to the trial participants or significantly affect the scientific value of the reported results of the trial. Examples of violations include but are not limited to:
- Failure to obtain informed consent (i.e. no documentation in source data or an Informed Consent Form).

- Enrolment of subjects that do not meet the inclusion criteria.
- Undertaking a trial or study procedure not approved by the REC and/or the MHRA (unless for immediate safety reasons).
- IMP dispensing/dosing error.

A violation could constitute a serious breach of the protocol and/or GCP or an urgent safety measure, see below for further definitions.

- 1.9.5. **Major Non-compliance or Breach** is a significant and unjustified departure from the protocol, SOP, GCP or regulatory requirements that may not have developed into a critical issue but may have the potential to do so unless addressed. Where there are a number of instances of deviations within a single area of responsibility, this indicates a systematic quality assurance failure and so should be collectively treated as a breach.
- 1.9.6. **Serious Breach** is defined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (“the Clinical Trials Regulations”) Regulation 29A (2), as amended by the Medicines in Human Use (Clinical Trials) (Amendment) Regulations 2025 (referred to as the “amended Clinical Trials Regulations”) Section 19, a breach which is likely to effect to a significant degree:
 - The safety or physical or mental integrity of the participants of the trial; or,
 - The scientific value of the trial.
- 1.9.7. **Urgent Safety Measures** are actions that the Sponsor and/or Investigator may take in order to protect the participants of a clinical trial against any immediate hazard to their health and safety.
- 1.9.8. **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, SOPs, GCP and the applicable regulatory requirement(s).
- 1.9.9. **Monitoring Report** is a written report from the monitor to the sponsor after each site visit and/or other trial-related communication according to the sponsor’s SOPs.
- 1.9.10. **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.

- 1.9.11. **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).
- 1.9.12. **Contract Research Organisation (CRO)** is defined as a person or an organisation (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.
- 1.9.13. **Clinical Research Associate (CRA)** is a person employed by a sponsor or a CRO acting on a sponsor's behalf, who is responsible for setting up, coordinating and monitoring clinical trials, ensuring that they are conducted in compliance with the regulatory requirements, Good Clinical Practice (GCP), and the study protocol.
- 1.9.14. **Clinical Study** - The European Union Clinical Trials Regulation (Regulation (EU) no 536/2014) Chapter I, Article 2 differentiates between clinical studies and clinical trials. Regulation (EU) no 536/2014, Chapter I, Article 2 (2 (1 (a-c))) defines a clinical study as any investigation in relation to humans intended:
- To discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products. Or,
 - To identify any adverse reactions to one or more medicinal products. Or,
 - To study the absorption, distribution, metabolism and excretion of one or more medicinal products.

With the objective of ascertaining the safety and/or efficacy of those medicinal products.

- 1.9.15. **Clinical Trial** - The European Union Clinical Trials Regulation (Regulation (EU) no 536/2014), Chapter I Article 2 (2 (2 (a-c))) defines a clinical trial as any research which fulfills any of the following conditions:
- The assignment of the subject to a particular therapeutic strategy is decided in advance and does not fall within normal clinical practice of the Member State concerned. Or,
 - The decision to prescribe the investigational medicinal products is taken together with the decision to include the subject in the clinical study. Or,
 - Diagnostic or monitoring procedures in addition to normal clinical practice are applied to the subjects.

- 1.9.16. **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.
- 1.9.17. **Investigator Site File (ISF)** contains the essential documents which show that the investigator and the conduct of the study are following the regulatory requirements. The ISF can be held in paper or digital formats, or a combination of both.
- 1.9.18. **Hosted** refers to an externally sponsored study for which the RCHT is acting as a research site.
- 1.9.19. **Datix Handler** is the person responsible for allocating responsibility for the investigation of an incident reported in the Trust's Datix incident management system.
- 1.9.20. **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.
- 1.9.21. **Quality Assurance Database (QuAD)** is a research database, developed by RCHT. The purpose of the database is to record all findings from monitoring reports, provide an overview of governance performance and ensure there is a robust audit trail to meet MHRA inspection expectations.
- 1.9.22. **Standard Operating Procedure (SOP)** is a procedure document detailing a specific sequence of events that must be followed for an activity.
- 1.9.23. **Glossary of Terms (R and D AD07)** is a glossary of the terms, and the definition of the acronyms can be found in the Associated Documents folder in EDGE.
- 1.9.24. **Acronyms**
- **CI:** Chief Investigator.
 - **CRA:** Clinical Research Associate.
 - **CRO:** Contract Research Organisations.
 - **CTIMP:** Clinical Trial of an Investigational Medicinal Product.
 - **GCP:** Good Clinical Practice.
 - **HRA:** Health Research Authority.
 - **ICH GCP:** International Council for Harmonisation (ICH) of Good Clinical Practice (GCP) Guidelines.
 - **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.
- **TMF:** Trial Master File.

1.10. This version superseded any previous versions of this document.

2. Purpose of this Standard Operating Procedure

The purpose of this document is to describe the process of reporting and managing non compliances and serious breaches upon identification. This includes guidance on the procedure for reporting to the appropriate regulatory bodies and other stakeholders.

3. Ownership and Responsibilities

3.1. Role of the R and D Clinical 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

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 all serious breaches and major non-compliance episodes are reported and investigated within the required timeframes outlined in Section 4.

- Ensuring adequate investigations are conducted for all episodes of non-compliance and appropriate corrective actions are implemented to prevent or reduce recurrence.
- 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.
- Supporting the Principal Investigator (PI) to fulfil the duties, responsibilities and obligations in executing the processes described in Section 4, Standards and Practice.
- Arranging monitoring and auditing of the systems and processes associated with the standards and practice described in Section 4.

3.3. Role of the Research Governance Manager

The Research Governance Manager is responsible for:

- Ensuring that information for serious breaches and major non-compliance is reviewed in a timely manner and that the event can be reported within the appropriate timelines, detailed in Section 4.4 Standards and Practice.
- Ensuring a report of a major non-compliance or serious breach is added to R and D's Non-compliance Log and updated with all significant information relating to the episode.
- Supporting the Head of R and D to appoint an appropriate person to undertake an investigation of a serious breach.
- Informing SMT of all reported episodes of non-compliance in the monthly governance report.

3.4. 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. In a multi-site study, the CI has co-ordinating responsibility for reporting serious breaches to the Medicines and Healthcare products Regulatory Agency (MHRA) and to the relevant Research Ethics Committee (REC). The CI is responsible for ensuring:

- All serious breaches are reported to the sponsor, MHRA, REC and R and D within the required timelines outlined in Section 4.
- The sponsor is provided with details of incidences and subsequent investigations of major non-compliance and serious breaches.
- Serious Breach reports from incident investigators are reviewed and evaluation performed with respect to the seriousness of the incident and adequacy of the measures which have been put in place.

- The sponsor, MHRA, REC and R and D department are supplied with any supplementary information, as requested.

3.5. Role of the Principal Investigator

The PI is responsible for:

- Ensuring the conduct of the study or trial is compliant with the study or trial specific protocol, the applicable regulatory requirements and adheres to the principles of Good Clinical Practice (GCP).
- Ensuring robust study or trial specific systems and processes are in place for recording, managing and reporting non-compliance.
- 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), REC and where appropriate the MHRA.
- Taking urgent safety measures where appropriate to ensure the safety of the participants.
- Ensuring all suspected and confirmed episodes of non-compliance are fully and appropriately investigated.
- Ensuring all episodes are classified and processed in accordance with the standards and practice described in Section 4.
- Ensuring all major episodes of non-compliance are recorded on the Trust's incident reporting system (Datix).
- Ensuring all suspected or confirmed serious breaches are reported immediately to Head of R and D, the Lead Research Nurse and the Research Governance Manager.
- Ensuring the sponsor is informed of all episodes of non-compliance in accordance with regulatory requirements and the principles of Good Clinical Practice (GCP).
- Supporting the regulators and auditors with queries relating to episodes of non-compliance.

3.6. Role of the Team Leader

The Team Leader is responsible for:

- Informing the PI of all suspected or confirmed episodes of non-compliance.
- Supporting the PI to ensure all staff involved in the trial or study fulfil the duties, responsibilities, and obligations in executing the processes described in Section 4, Standards and Practice in accordance with the principles of GCP.

- Identifying training needs for RCHT staff involved in the standards and processes described in Section 4.
- Ensuring episodes of non-compliance are recorded and reported in accordance with the requirements of the sponsor and regulatory requirements, described in Section 4.
- Supporting the incident investigating officer to ensure that all suspected and confirmed episodes of non-compliance are fully and appropriately investigated.
- Supporting monitors, regulators, auditors, investigators and other persons undertaking official duties, with queries relating to episodes of non-compliance.

3.7. Role of the Research Nurse

The Research Nurse is responsible for:

- Informing the PI and Team Leader of all suspected or confirmed episodes of non-compliance.
- Supporting the incident investigating officer to ensure that all suspected and confirmed episodes of non-compliance are fully and appropriately investigated.
- Ensuring episodes of non-compliance are recorded and reported in accordance with the requirements of the sponsor and regulatory requirements, described in Section 4.
- Supporting monitors, regulators, auditors, investigators and other persons undertaking official duties, with queries relating to episodes of non-compliance.

3.8. Role of the Governance Officer

The Governance Officer is responsible for:

- Identifying any episodes of non-compliance when conducting internal audits and monitoring activities for sponsored studies (See R and D SOP003 Internal Audit Plan).
- Identifying any episodes of non-compliance reported in the Monitoring Reports and recording the episodes of non-compliance using R and Ds quality assurance database (QuAD).
- Informing the relevant Team Leader and Research Governance Manager of all suspected or confirmed episodes of non-compliance.
- Ensuring episodes of non-compliance are recorded and reported in accordance with the requirements of the sponsor and regulatory requirements, described in Section 4.

- Supporting the Research Governance Manager to maintain and review the R and D Non-compliance Log.

3.9. Role of the Datix Handler

The Datix Handler is responsible for:

- Identifying an appropriate person to undertake investigations of episodes of major non-compliance.
- Ensuring Datix incidences are investigated in accordance with the Trust's Patient Safety Incident Response Policy.
- Informing SMT of the reported Datix incidences and investigation outcomes in the monthly governance report.

3.10. Role of the individual

The individual is responsible for:

- Informing a member of SMT of all suspected or confirmed episodes of non-compliance.
- Supporting the incident investigating officer to ensure that all suspected and confirmed episodes of major non-compliance are fully and appropriately investigated.
- Supporting monitors, regulators, auditors, investigators and other persons undertaking official duties, with queries relating to episodes of non-compliance.

4. Standards and Practice

4.1. Identification of a non-compliance or deviation and immediate reporting requirements

- 4.1.1. Non-compliance or deviations may be identified by anyone involved in the conduct, management or monitoring of a clinical trial or study. Members of a research team may receive information relating to a potential non-compliance or deviation directly or indirectly.
- 4.1.2. In many instances, suspected episodes of non-compliance will be identified in retrospect through monitoring and audit activities. During monitoring and auditing visits staff working on the study or trial should support the monitor or auditor to identify and resolve potential episodes of non-compliance.
- 4.1.3. Once an episode of major non-compliance is suspected or confirmed, it should be reported to the Principal Investigator (PI) or a member of the SMT within 24 hours or as soon as possible after becoming aware of the event.

- 4.1.4. When non-compliance is suspected, further information should be gathered detailing the nature and extent of the episode. All information which is relevant to the major non-compliance should be documented.
- 4.1.5. It is the sponsor's responsibility to refer to the trial or study specific protocol and MHRA guidance in order to assess whether the major non-compliance constitutes a serious breach.

4.2. Reporting and Management of a Major Non-compliance

- 4.2.1. It is the sponsor's responsibility to assess whether the major non-compliance episode should be treated as a serious breach and refer to the process outlined in section 4.3 if appropriate.
- 4.2.2. An appropriate person must report episodes of major non-compliance on the Datix incident reporting system in accordance with the requirements of Trust's Patient Safety Incident Management Policy.
- 4.2.3. The R and D Datix Handler will assign an appropriate incident investigator, usually a Team Leader or a member of SMT. All investigations should be completed within 10 working days of the incident being reported. Consideration should be made as to whether this incident should be formally notified to the sponsor.
- 4.2.4. The incident investigator will conduct a root cause analysis to establish the fundamental reason for the occurrence of the incident. Details of the investigation should be updated in the Datix incident reporting system.
- 4.2.5. SMT will maintain oversight of the reporting and management of incidents of major non-compliance through monthly governance reports.

4.3. Reporting and Management of a Serious Breach

- 4.3.1. Appendix 3, Flowchart for Reporting a Serious Breach, details the process for reporting a serious breach, for hosted and sponsored trials and studies.
- 4.3.2. The sponsor should be notified within 24 hours of the serious breach being identified if a major non-compliance is considered to be serious or there is doubt regarding the classification.
- 4.3.3. An appropriately trained person must immediately report the serious breach on the Datix incident reporting system in accordance with the Trust's Patient Safety Incident Management Policy.
- 4.3.4. An appropriate person should report the serious breach to the Head of R and D and the Lead Research Nurse via rcht.researchmanagement@nhs.net and the Research Governance Office via rcht.researchqualityassurance@nhs.net, ensuring the email subject header includes 'SERIOUS BREACH'.
- 4.3.5. The Head of R and D or the Lead Research Nurse will assign an incident investigator for the serious breach (see Section 4.5 Investigating Serious breaches).

- 4.3.6. It is a legal requirement that all serious breaches for MHRA notifiable clinical trials, are reported to the MHRA by the sponsor within seven days of the sponsor becoming aware of the breach.
- 4.3.7. Although not a legal requirement, the Research Ethics Committee (REC) that originally granted approval should also be notified by the sponsor within seven days of the sponsor becoming aware of the serious breach, both for CTIMP and Non-CTIMP studies.

4.4. Reporting and Management of Urgent Safety Measures

- 4.4.1. Upon identifying a hazard to research participants, requiring immediate action to protect their health and safety, the PI or appropriately delegated person should consider putting urgent safety measures in place to protect the participants.
- 4.4.2. Wherever possible the PI or appropriately delegated person should refer to the protocol for any specific urgent safety measures instructions.
- 4.4.3. Urgent safety measures can be implemented immediately. Notifications and/or approvals are not required prior to implementation.
- 4.4.4. Upon implementing urgent safety measures, the PI or appropriately delegated person must inform the sponsor immediately. The PI or appropriately delegated person should follow the instructions set out in the study protocol for reporting urgent safety measures. Where there are no instructions, the PI or appropriate delegated person should document all decisions and notify the sponsor. The sponsor will assess whether MHRA and REC notification is required.
- 4.4.5. For locally sponsored studies, any urgent safety measure relating to a CTIMP should be communicated to the MHRA immediately. Sponsors should phone the MHRA Clinical Trial Unit within 24 hours to discuss the event with the medical assessor. The sponsor must follow up with the notification in writing within three days of the action being taken. The notification should be in the form of a substantial amendment and should describe the event, the measures taken and the justification for the measures taken. <https://www.ct-toolkit.ac.uk/routemap/urgent-safety-measures>
- 4.4.6. All incidents should be logged on the Datix system for local governance and oversight, even if sponsor reporting systems are used. The PI or appropriately delegated person must immediately report the incident requiring urgent safety measures on the Datix incident reporting system in accordance with the Trust's Patient Safety Incident Response Policy. <http://doclibrary-rcht-intranet.cornwall.nhs.uk/DocumentsLibrary/RoyalCornwallHospitalsTrust/Clinical/PatientSafetyAndClinicalEffectiveness/PatientSafetyIncidentResponsePolicy.pdf>

- 4.4.7. Report the Urgent Safety Measure to the Head of R and D and Lead Research Nurse via rcht.researchmanagement@nhs.net and the Research Governance Office via rcht.researchqualityassurance@nhs.net, ensuring the email subject includes 'URGENT SAFETY MEASURES'.

4.5. Investigating Serious Breaches

- 4.5.1. Following the notification to the appropriate regulatory authorities, the Head of R and D or the Research Governance Manager will appoint someone to carry out an investigation into the root cause of the serious breach.
- 4.5.2. The investigation will collect evidence and accounts from those involved in order to produce a full report of the incident including timelines, events and the impact of the breach on participant safety and/or the integrity of the trial.
- 4.5.3. The investigation should be completed and a report submitted to the Head of R and D or the Research Governance Manager within 10 working days of the investigating officer being assigned. The investigating officer should inform the Head of R and D or the Research Governance Manager of any potential delays in completing the investigation.
- 4.5.4. Corrective and Preventative Action(s) (CAPA) will be developed, detailing action(s) to be implemented to address the immediate issues and to prevent the breach from happening again.
- 4.5.5. A final report from the REC and MHRA (if applicable) will be submitted to the Senior Management Team (SMT) for review. The internal investigation report and CAPA should also be submitted to SMT for review, ensuring oversight and that all learning opportunities are utilised.

4.6. Documenting Non-compliance

- 4.6.1. A record of all non-compliance and a copy of all documents relating to the episode, including correspondence, should be filed in the Investigator Site File (ISF) for hosted studies and the Trial Master File (TMF) for sponsored studies.
- 4.6.2. Episodes of non-compliance notified in an external monitoring or audit report will be added to the QuAD. Copies of monitoring and audit reports should be filed in the ISF.
- 4.6.3. Episodes of major non-compliance and serious breaches should be added to the R and D Non-compliance Log by the Research Governance Manager or the Research Governance Officer.

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 and external monitoring of research studies and clinical trials will monitor 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.
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 SOP004 Reporting and Managing Non-compliance and Serious Breaches V5.0
This document replaces (exact title of previous version):	Non-compliance Reporting 08 Research and Development Standard Operating Procedure V4.0
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 SOP describes the processes of reporting and managing non compliances and serious breaches upon identification. This includes guidance on the procedure for reporting to the appropriate regulatory bodies, Research Ethics Committee and other stakeholders.
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 CIOs 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)

Information Category	Detailed Information
Manager confirming approval processes:	Bianca Mills, Head of Research and Development
Name of Governance Lead confirming consultation and ratification:	Caroline Phillips – Research Governance Manager
Links to key external standards:	Good Clinical Practice for Clinical Trials 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 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/ Regulation (EU) No 536/2014 of the European Parliament and of the Council Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (Text with EEA relevance) International Council for Harmonisation Guideline for Good Clinical Practice E6 (R3) (06 January 2025) ICH E6(R3) Step4 FinalGuideline 2025 01 06.pdf MHRA Good clinical practice for clinical trials https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials Guidance for the notification of serious breaches of GCP or the trial protocol https://assets.publishing.service.gov.uk/media/5f22f594e90e071a603d33f4/Guidance_for_the_Notification_of_Serious_Breaches_of_GCP_or_the_Trial_Protocol_Version_6_08_Jul

Information Category	Detailed Information
	_2020.pdf Patient Safety Incident Response Policy http://doclibrary-rcht-intranet.cornwall.nhs.uk/DocumentsLibrary/RoyalCornwallHospitalsTrust/Clinical/PatientSafetyAndClinicalEffectiveness/PatientSafetyIncidentResponsePolicy.pdf Clinical Trials Toolkit, Urgent Safety Measures https://www.ct-toolkit.ac.uk/routemap/urgent-safety-measures R and D SOP001 Preparation, Approval and Review of Standard Operating Procedures (SOPs) and Work Instructions (WIs). R and D SOP003 Internal Audit Plan. R and D AD07 Glossary of Terms. R and D AD19 Training Matrix.
Training Need Identified:	Yes – Details provided in Section 5.
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet.
Document Library Folder/Sub Folder:	Research and Development.

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
01/07/2014	V1.0	2 Year Review	Dr N Morley, R and D ARM.
01/07/2014	V2.0	Complete revision to reflect current practice	Dr N Morley, R and D ARM
27/04/2017	V3.0	'Policy Under review' label added.	Helen Holman, Data Quality and Project Monitoring Officer.
01/08/2017	V3.0	Complete rewrite to align with Trust policies	Dr N Morley, R and D Assistant Research Manager.
01/06/2021	V4.0	Review and update in accordance with RCHT policies	Dr N Morley, R and D Assistant

Date	Version Number	Summary of Changes	Changes Made by
			Research Manager.
14/08/2025	V5.0	Changes from RD and I to R and D. Review of SOP in line with GCP guidance, feedback from external monitoring and audits and changes to R and D procedures. Review and update in accordance with Trust policies.	Caroline Phillips, Research Governance Manager.

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust [The Policy on Policies \(Development and Management of Knowledge Procedural and Web Documents Policy\)](#). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity, and Inclusion Team
rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Research and Development SOP004 Reporting and Managing Non-compliance and Serious Breaches V5.0
Department and Service Area:	Research and Development. Corporate.
Is this a new or existing document?	Existing.
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Caroline Phillips, Research Governance Manager.
Contact details:	rcht.researchqualityassurance@nhs.net 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 SOP describes the processes of reporting and managing non compliances and serious breaches upon identification. This includes guidance on the procedure for reporting to the appropriate regulatory bodies, Research Ethics Committee and other stakeholders.
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 and monitoring programme to ensure that research studies are compliant with GCP. External monitoring and auditing carried out by the Sponsors and Clinical Research Associates (CRAs).

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

7. The Impact

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

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

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

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

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

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

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

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

Appendix 3. Flowchart for Reporting a Serious Breach

