STANDARD OPERATING PROCEDURE

S67 – Corrective and Preventive Action (CAPA)

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Controlled document

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DISCLAIMER

This generic R&D Standard Operating Procedure (SOP) must be followed unless a study specific SOP exists.

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Full History			
Version	**Date**	**Author**	**Reason**
1	July 2022	Quality Assurance Manager	New policy to support R&D standards.

Associated Trust Policies/ Procedural documents:	S05 - NOTIFICATION OF SERIOUS BREACHES OF GCP OR STUDY PROTOCOL
Key Words:	Breach CAPA Correction Corrective Action Deviation Non-Compliance Preventive Action
In consultation with: R&D Governance Oversight Group (GOG) – July 2022 QA Group – July 2022	

Contents

1. INTRODUCTION

The Royal Devon University Healthcare NHS Foundation Trust (Royal Devon) Quality System is required to include procedures to correct deficiencies and incidents of non-compliance and identify the cause to prevent re-occurrence.

2. PURPOSE

This document describes the procedure for raising and completing Corrective and Preventive Actions (CAPAs) within Research & Development (R&D) for hosted and sponsored studies.

3. SCOPE

This procedure applies to the analysis of Corrective and Preventive information and actions arising from, but not limited to, internal & external monitoring activities. Other sources may include audits, incidents and complaints.

Corrective and Preventive Actions may impact on any aspect of the Quality System or associated documentation.

Protocol and GCP serious breaches are covered by S05; therefore, if there is an escalation beyond the information in S05 then this CAPA process should be followed.

4. DEFINITIONS & ABBREVIATIONS

Breach	A departure from agreement, law, obligation or conduct.
CAPA	Corrective and Preventive Action
CI	Chief Investigator
Correction	Action to eliminate a detected breach/deviation
Corrective Action	Action to eliminate the cause of a detected breach/deviation and prevent re-occurrence
Deviation	Change, divergence, or departure from any written procedure.
GCP	Good Clinical Practice
GOG	R&D Governance Oversight Group
Initiator	Individual who identified the potential CAPA
Non-Compliance	Non-fulfilment of specific requirements
Owner	Person responsible for implementing Corrective/Preventive Actions
PI	Principal Investigator
Preventive Action	Action to eliminate the cause of a potential breach/deviation
R&D	Research & Development
Royal Devon	The Royal Devon University Healthcare NHS Foundation Trust
SME	Subject Matter Expert - person with the working knowledge of the system affected by the breach/deviation or Preventive Action.
SOP	Standard Operating Procedure
Sponsor	An individual, company, institution or organisation which takes responsibility for the initiation, management and financing of a clinical trial. Sponsorship activities may be delegated to the Investigator, CTU and/ or other organisations as appropriate
TMF	Trial Master File

5. DUTIES AND RESPONSIBILITIES OF STAFF

The Governance and Oversight Group (GOG) will provide oversight of the actions undertaken and completed for Corrective and Preventive Actions.

The Quality Assurance Manager is responsible for the overall operation of the systems to assess, formulate, implement and review Corrective and Preventive Actions.

The Owner is the person responsible for devising, implementing and seeing the Corrective/Preventive Actions through to completion. This will be jointly agreed with the Quality Assurance Manager within a specified time period. The Owner may be a Manager or Investigator.

The Quality Assurance Coordinators will oversee R&D CAPAs and monitor progress using Q-Pulse. This will include recording and tracking progress at agreed time points until completion is reached, as set out in the action plan.

6. PROCEDURES

6.1 CAPA Identification

6.1.1 The need for Corrective/Preventive Action within the scope of this procedure is identified from one or more of the following Quality Systems:

- Internal monitoring
- External monitoring
- Audits
- Actions from management meetings
- Deviation management
- Risk assessments
- Complaints
- Incidents

6.1.2 Evaluate the need for action. The degree of formality and effort involved with CAPA implementation should be commensurate with the magnitude and risk of the observed or potential breach/deviation.

6.1.3 CAPAs will be reviewed by the QA Manager (or designate) to assess the information supplied and determine if actions are acceptable prior to raising the issue on the CAPA Tracking and Monitoring database.

6.2 Initiation

The Initiator must highlight the breach/deviation to either a Manager, or CI/PI if in relation to a study. This should then be escalated to the QA Manager who will identify a potential 'Owner' for the CAPA and support them in initiating the CAPA process as well as advising on the effectiveness of the actions identified.

The Owner is considered to be the Subject Matter Expert for the process affected and is identified based upon the area/process in which the breach/deviation was found, or upon the type of action.

6.3 Investigation

6.3.1 Following allocation of the CAPA to the Owner, an investigation should be conducted to ensure that the cause is clearly defined and documented, and a suitable action plan is identified to reduce the risk of the breach or deviation occurring or reoccurring in the future.

6.3.2 A timeline for progressing the CAPA will be agreed between the Owner and the QA Manager. If the breach/deviation in question relates to a regulatory or other external body then additional set timelines may need to be complied with.

6.3.3 The investigation process is about establishing fact, not finding fault.

6.4 Implementation

The Owner (working with the QA Manager) is required to:

- Implement the **action plan** within the agreed timescales.
- Fully document evidence of actions taken.
- Effectiveness Checks should be conducted by the Owner after a sufficient interval of time has elapsed for the relevant Corrective or Preventive Actions to be evaluated, and for effectiveness to be demonstrated.
- If an external organisation (i.e. MHRA) or the protocols of a hosted study require their CAPA form to be completed, use their version but ensure copies of the completed forms are saved and accessible to all relevant people.

All CAPAs will be notified to GOG by a nominated lead as part of the Quality Assurance governance report, and assurance will be provided regarding the actions undertaken and completed for the CAPAs.

6.5 CAPA Closure

6.5.1 The closure of a CAPA is a 2-step process. When the Owner deems that the CAPA is completed, they must confirm:

- Action plan completion.
- No reoccurrence of the original breach/deviation.

6.5.2 Once the Owner has confirmed completion of the action plan, the QA Team is required to:

- Devise and implement a follow up plan, the timings of which will depend on the nature of the CAPA.
- As part of this, follow up checks will be carried out to confirm that the original action plan was completed and implemented as agreed and to verify that the actions taken have been effective.
- Evaluation timescales must be clearly defined at the time of action plan creation.
- Effectiveness Checks must confirm that the CAPA has achieved the aim of:
    - Reducing/stopping recurring breaches/deviation.
    - Ensuring that the action plan was free from unintended negative effects that may have caused new problems in other areas/systems.
    - Evidence of effectiveness may take the form of observations, records or data.

7. DISSEMINATION AND TRAINING

7.1 This SOP and associated templates and forms will be uploaded to the Royal Devon website shortly after having been released.

7.2 All staff whose activities are subject to this SOP should ensure that they take time to read and understand the content of this SOP.

7.3 *If applicable, a training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the contents of this SOP.*

8. MONITORING COMPLIANCE AND EFFECTIVENESS OF THIS SOP

8.1 In order to monitor compliance with this SOP, the auditable standards will be monitored as follows:

No	Minimum Requirements	Evidenced by
1.	CAPA implementation considered by QA Manager.	Documented breach/deviation presented to QA Manager and evidence of consideration e.g. QA meeting minutes.
2.	Compliance times for each stage of CAPA set out in initial action plan.	Spot check of CAPA documentation.
3.	Effectiveness checks must confirm that the action plan was completed and implemented as agreed.	QA Manager documented review as part of CAPA closure.

8.2 Outcomes from audit will be presented to the R&D Governance Oversight Group (GOG) which will monitor any resulting action plans until all issues have been addressed to satisfaction.

8.3 Issues identified via the audit process which require escalation will be referred to GOG.

9. ARCHIVING ARRANGEMENTS

9.1 The original of this document will remain with the R&D Quality Assurance Coordinator. An electronic copy will be maintained on the R&D section of the Q-Pulse document management system and a pdf copy on the Royal Devon website.

9.2 Archive copies must be maintained for any documents which have been superseded. Archive copies in electronic format should be retained indefinitely.

10. REFERENCES

11. APPENDIX 1

FRM 75 Corrective Action and Preventive Action (CAPA) Plan

Study (or non-related study) Title	
Responsible person (e.g. CI, Local PI)	

Details of deficiency or non-compliance e.g. What happened and what was observed? What should have happened?	**Date of deficiency or non-compliance:**	**CAPA Reference No.**
• • •		
CAPA Owner	**CAPA Initiator**	

	Action(s)	Corrective or Preventative?	Due Date	Responsible person	Notes	Date action complete
1						
2						
3						
4						
5						

Effectiveness of Actions

Evidence Actions have resolved the deficiency/non-compliance(s):

-
-
-

Deficiency/non-compliance resolved? **Yes** ☐ **No** ☐

If no, detail next steps:

Confirmation of CAPA Closure			
Date CAPA closed	**Confirmed by**	**Role**	**Signature**
Confirmation of No Reoccurrence of CAPA			
Date CAPA closed	**Confirmed by**	**Role**	**Signature**

Quality Assurance Confirmation of CAPA closure	
Name:	
Role:	
Signature:	**Date:**