STANDARD OPERATING PROCEDURE

S68 - Research & Development Change Control SOP

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Author & Position	David Evans, Quality Assurance Manager
Signature	D. Evans
Date	02/8/22
Approver & Position	Helen Quinn, R&D Director
Signature	
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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.

Once printed this is an uncontrolled document

Full History			
Version	**Date**	**Author**	**Reason**
1.0	27/07/2022	David Evans	New SOP

Associated Trust Policies/ Procedural documents:	*https://www.royaldevon.nhs.uk/about-us/research-and-development/information-for-researchers/useful-documents/*
Key Words:	Change Control R&D SOP
In consultation with: • Quality Assurance Group • Governance and Oversight Group (GOG) • Operational Management Group (In consultation with)	

Contents

1 INTRODUCTION

An identified change to a research study will follow the procedures within the study protocols. Change control is important as it gives stakeholders an opportunity to participate in control of any changes required and provides an audit trail of the change implemented. However, if change is required to operational procedures that are not specifically linked to a research study then the following full change control procedure will be implemented and the associated documentation completed.

Minor changes to processes, equipment or environment etc. do not require full change control documentation. However, the impact of the change still needs to be considered.

2. PURPOSE

To establish a procedure for controlling and documenting procedural changes that are not study specific and to adhere to regulatory and legislative requirements whilst ensuring a consistent approach when implementing change.

This procedure has been introduced to ensure a full record of change control for all significant changes within the department and ensure that suitable and trained individuals are involved in the process and that it is carried out in a timely manner. The completed record sheets must be retained. Before any change is implemented, the implications of the change need to be analysed and understood, both for the end user and for the staff in the department involved in that change.

In order to do this a record of change control documentation has been developed to make the decision-making process easier and consistent and will be used for all required changes outside of a research protocol. Change control should relate to systems, processes or documents that could impact on quality and/or compliance.

3. SCOPE

This SOP applies to all members of staff within R&D.

4. DEFINITIONS & ABBREVIATIONS

CTIMP	Clinical Trial of an Investigational Medicinal Product
GOG	R&D Governance Oversight Group
Initiator	A person who identifies the requirement for a significant change and initiates the change control process
Minor Change	Changes to controlled documents including SOPs which only affects a single document and does not require significant retraining (managed by document control system); changes which do not have an impact on regulatory compliance etc…
QA	Quality Assurance
R&D	Research & Development
Significant change	Changes that are temporary planned deviations from approved procedures; changes that may impact service across more than one team and/ or department where coordination of efforts is required; changes that may have potential impact on patient safety etc.
SOP	Standard Operating Procedure

5. DUTIES AND RESPONSIBILITIES OF STAFF

All research staff have a responsibility to identify and report required changes in procedures, processes and legislation.

- The R&D Governance Oversight Group (GOG) will provide oversight of the change request and approve the proposed change(s).
- The Quality Assurance (QA) team is responsible for co-ordinating the requested change, ensuring the correct documentation has been completed and the change control procedures within this SOP have been followed.
- The team leader responsible for the area affected by the change is responsible for ensuring all critical aspects and significant changes are implemented following the change control process
- The person proposing the change is responsible for ensuring all aspects of the change control form are completed.

6. PROCEDURES

6.1 Initiating Change Control

To begin the process for initiating change control a discussion should be held by the initiator of the change with a senior manager/managers and other relevant people that would be affected by the change. The initiating process should discuss the change, the wider impact of the change, agree the change is necessary and can be implemented.

All change control proposals should be reviewed at the responsible department's team meeting and the date of the meeting where the change was reviewed should be recorded on the change control form.

There may be occasions where a change is time critical and therefore cannot be discussed at the proposal stage during the regular team meeting. The changes should be discussed with the senior management team and assigned a designated approver. The change control process can proceed but should be discussed at the departmental meeting at the first available opportunity.

6.2 Risk Assessment

A risk assessment must be completed if there is a significant risk or risks for the change control. The risk assessment should assess both the risk of the proposed change and the risk of not implementing the change.

Follow the Trust risk assessment process, using the Trust's risk assessment template, located on The Hub: Trust Risk Assessment Template (Appendix 5a

within Trust Risk Assessment SOP)

The risk assessment should be submitted as part of the initial proposal approval and should be saved with the change control form for future reference.

6.3 Proposal Approval

Once steps 6.1 and 6.2 have been completed, the proposal and risk assessment should be sent to the designated Approver, who should be a senior manager within the department affected by the change. The Approver will then sign and date the change control request form (FRM76) confirming if the change is approved or rejected.

The next stages of change control should not be completed until the proposal is approved.

If the change control request is not approved, a reason for the non-approval should be communicated to the Initiator, the reason recorded and saved if required for future reference

6.4 Wider Impact of Change

After the change control request has been agreed by the designated Approver, the QA team will review the proposed change to establish if the change will have a wider impact on other departments and teams beyond the Initiator's team.

The QA team will also check the proposed change meets regulatory requirements, GCP requirements and any other approved guidance. Plus ensure there is no conflict with information or procedures detailed in existing SOPs.

6.5 Completing the Change Control Form

When agreement to the change control has been obtained, the Change Control Initiator should complete the change control form (FRM 76 Change Control - Appendix 1) to initiate the change request and submit to the QA team.

The reason for the change, what the change will achieve and the expected benefits of the change should be included. Relevant references such as guidelines, legislation, audits or incidents that have led to consideration of the change should be included. Costing or budget implications should also be outlined here.

On receipt of the change control form, the QA team will allocate a change control reference and record the details of the change control. The QA team will confirm the approval of the change request to the Initiator and liaise with them through the process of implementing the change.

6.6 Implementation of Change Control

The Initiator should create a plan of the required activities to be completed to ensure the change is implemented correctly (use section 6 of the change control form). The target date for completion of the activity and the person responsible for completing the activity should be included with the plan.

Evidence of completion of each activity should be recorded and saved for review and evaluation.

The Initiator should advise the QA team when all the activities required to implement the change have been completed.

6.7 Tracking and Reporting by QA

Regular reviews of the change activity plan shall be conducted by the QA team to evaluate completion and implementation of activities.

If the change control cannot be implemented fully within the agreed time period, the person/department responsible for the completion of the activity should request via their senior manager an extension to the completion date for the activity. Or an extension to the implementation date for the entire change control if applicable. Any request to extend the completion date for an activity or the entire change control should detail the justification and impact of the extension.

The senior manager and QA Manager will assess the impact of the extension and advise accordingly if the extension has been approved or rejected.

6.8 Post Implementation Effectiveness Checks

After the implementation of the change, a Manager within the department affected and a member of the QA team should complete a post implementation evaluation of the change. To ensure the objective(s) of the change have been achieved and that there has been no adverse impact.

After satisfactory evaluation of the change implementation the change control request can be closed.

6.9 Closing a Change Control Request

Once the change request has been documented, communicated, implemented and all actions have been completed, the request is ready to be closed. The information relating to the change request e.g. any documentation, change control records, communications etc… should be saved in an accessible place by the QA team which can be accessed for future reference if required.
The QA team will periodically review the record of change control requests to ensure they have been completed and closed appropriately.

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.	A risk assessment (if required) has been completed.	Document stored on the R&D drive and in the TMF
2.	The Change Control request form (FRM76) has been signed by the Approver.	Documents retained in TMF
3.	The change control form (FRM 76) has been completed and a reference number added. And approval sent by the QA team to the Approver.	Documents stored on the R&D drive and in the TMF
4.	An action plan has been created with target dates and saved in an accessible location.	Documents retained in the TMF

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

Appendix 1 – Change Control Form (Ref No. FRM 76)

Department:		**Change Requestor's Name**		**Date Started:**	

If a step is not appropriate for this change control process, enter N/A in the response/comments box

Change Proposal

Step 1 - Details of change	**Response / Comments**	**Person Responsible**	**Target Date**	**Date Completed**
Existing system/process				
Proposed Change(s)				
Reason/Justification for Change(s)				
What are the expected benefits?				
Are there any risks to this change? (If there is a significant risk or risks, follow the Trust's risk assessment process)				

What are costings/budget implications?				
Will the change impact on other teams/departments? Detail if yes.				
APPROVAL: **I confirm that I have approved this change request:** (Person responsible approving the changes i.e. R&D Manager, Assistant R&D Manager, QA Manager, Lead Nurse etc…)	**Name:** **Signed:**			

Step 2 - Documentation	Response / Comments	Person Responsible	Target Date	Date Completed
Existing Documentation Identified for the change: Have all associated documents been reviewed and updated as appropriate? (list documents updated) This MUST include any changes made to an existing SOP(s), Policy, Risk assessment, COSHH assessment, Checklist etc.				
New Documentation Identified for the change: Have all necessary documents been written? (list documents written) This MUST include all new documents such as SOP(s), Policy, Risk assessments, COSHH assessment, Checklist etc.				

Step 3 - Equipment	Response / Comments	Person Responsible	Target Date	Date Completed
Does the change require the alteration of existing or the introduction / purchase / acquisition of new equipment? (List equipment required) Has the equipment been validated prior to use? (Give details)				
Step 4 – Facilities and IT	**Response / Comments**	**Person Responsible**	**Target Date**	**Date Completed**
Does the change require the introduction of new facilities (furnishings or other refurbishment)? (Give details) Does the change require the introduction of new IT systems? Have these been validated prior to use? (Give details) Has the impact on departmental processes and/or other IT systems been assessed? (Give details)				

5. Communication & Training				
Have these changes been communicated to the relevant staff? (give details) Have staff received appropriate training? If so training records must be retained by the department. (list how this was assessed) Have the users of the service been informed of any changes that may impact on them?				

6. Action(s): List any associated actions below *(add additional lines if more actions are required)*

Action Description	**Allocated to:**	**Date to be completed**	**Completed? Y/N**	**Comments**
Action Description	**Allocated to:**	**Date to be completed**	**Completed? Y/N**	**Comments**
Action Description	**Allocated to:**	**Date to be completed**	**Completed? Y/N**	**Comments**

Sign off:	**Signed:**	**Date completed:**

I confirm that this change control Process is complete: (Person responsible for carrying out the Change request)	**Name:**	**Position:**
Approval: **I confirm that I have approved this change request and I agree with the Implementation:** (Person responsible for approving the changes)	**Signed:** **Name:**	**Date completed:** **Position:**
This change control process has been reviewed by the QA Manager	**Signed:** **Name:**	**Date:**