Dorset HealthCare University NHS Foundation Trust

Standard Operating Procedure for Preparation, Review, Approval and Issue of Standard Operating Procedures

Objectives	The objective of this SOP is to standardise the procedure for preparation, review, approval and issuing of SOPs.
Scope	This procedure is applicable to all Research & Development staff involved in the preparation, review, approval and issuing of SOPs.
Responsibility	The R&D Facilitator is responsible for ensuring implementation of this SOP within the Research & Development Department.
Related Document	DHC Standard Operation Procedure (SOP) Template.

1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to explain how to write, structure, issue and review local SOP documents for research activity at Dorset HealthCare University NHS Foundation Trust (DHC).

2 Introduction

A Standard Operating Procedure (SOP) is an instructional document that sets out the way a process/procedure must be performed.

This SOP describes the procedure for writing, approving and issuing SOPs, including the review and update of these SOPs.

SOPs are a regulatory requirement for those areas complying with Good Clinical Practice (GCP).

SOPs may be used across research in Dorset HealthCare University NHS Foundation Trust wherever instructions need to be documented.

3 Training

New users must read and understand this SOP before carrying out this procedure. Existing users must refer to the Revisions section and read the highlighted changes.

4 Revisions

This is the second version of this SOP.

5 Procedure

5.1 Format

All SOPs should be prepared according to a standard format, which is held by the Dorset HealthCare University Research & Development Department (electronic SOP template). A

unique reference number must be assigned to the SOP plus a version number and review dates. The Research & Development Department will hold SOP indices.

5.2 Content

The SOP must contain the following sections (other sections may be added, as appropriate):

- Purpose: to outline the purpose of the SOP.
- Introduction: to include a brief description of the procedure plus the scope of the SOP.
- Training: for a new SOP the following statement must be made: “Users must read and understand this SOP before carrying out the procedure.” For subsequent versions: “New users must read and understand the contents of this SOP. Existing users must read and understand the revisions section.”
- Revisions: a brief description of amendments must be given. If the SOP is version 1, state: “This is the first version of this SOP.”
- Procedure: a full description of the procedure must be given in a clear, step-wise manner.
- Appendices: list of appendices associated with the SOP.
- Responsibilities: individual responsibilities defined.
- Associated documents: cross-references to SOPs and a list of any other relevant documents.

5.3 Writing a SOP

A SOP should be written as soon as the need for a standard written procedure for an activity is identified.

SOPs should be written or co-written by a person competent to do so. The author/co-author of the SOP must be a person who performs the procedure regularly; it should be agreed by the Research & Development Facilitator, who should read and approve the procedure.

The procedure must be written in a clear, step-wise manner. The use of flow charts is encouraged.

If describing part of a clinical trial process, the SOP should identify at which stage of the trial the SOP applies.

Appendices must have reference numbers to tie them to the SOP to which they apply e.g. Appendix 1 for SOP DHC RES 001 version 1 must have a reference APP1 DHC RES 001 Version 1.0. Appendix 2 will be APP2 DHC RES 001 Version 1.0 etc.

SOPs will be stored on the DHC NHS FT ‘shared drive’ and on the DHC NHS FT Intranet.

5.4 Authorisation of SOPs

New or updated draft SOPs will be subject to review by an approved selection of staff that will use the SOP, to be nominated by the R&D Facilitator.

Any changes requested during the review process will be made to the draft as necessary. The SOP will then be submitted to the above mentioned staff for approval, and the SOP status changed from draft to active.

5.5 Issuing SOPs

The issue date is the date on which the SOP is approved, i.e., the date it becomes official and available for viewing by users.

The R&D Facilitator will inform all research-active staff about the updated and re-issued SOP, by email.

All relevant staff must have read and understood the SOP, or received specific training within one month of the issue date.

All research department staff will sign the SOP training log to confirm they have reviewed the SOP.

The SOP should be referred to electronically; only in exceptional circumstances should a hard copy be printed, which will only be valid for 5 days after printing, after which it must be destroyed.

N.B. It is forbidden to make copies of controlled copies.

5.6 Reviewing SOPs

Deficiencies requiring SOP amendments must be dealt with at the earliest opportunity and no later than the next scheduled SOP review.

N.B. All staff are responsible for identifying any deficiencies in the SOPs and reporting them to the R&D Facilitator so that the SOP may be updated.

The R&D Facilitator will arrange for appropriate SOPs to be prepared or existing ones modified to address these deficiencies, using the process outlined in this document.

The author must review SOPs annually with the R&D Facilitator, or whoever this is delegated to.

If no change requests have been raised at the date of annual review, the R&D Facilitator will update the review date and the version number will remain unchanged.

5.7 Superseded/withdrawn SOPs

Superseded SOPs will be saved on the DHC NHS FT ‘S shared drive.

6 Appendices

There are no appendices to this SOP.

7 Responsibilities

The R&D Facilitator is responsible for managing the review process for SOPs.

All staff must adhere to SOPs.

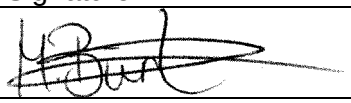
R&D Facilitator is responsible for ensuring that all staff are trained in relevant SOPs and that this is documented.

It is the responsibility of Principal Investigators to ensure that they, and co-investigators, are aware of the research SOPs, and that their research projects are managed and run in accordance with the SOPs. They are not required to sign a training log unless a study-specific SOP calls for this. Principal Investigators acknowledge the use of SOPs when signing the ‘PI Responsibilities Document’ upon receiving Trust permission for their individual research projects.

8 Review

This SOP should be reviewed every two years unless new guidance or legislation dictates a review any sooner.

Date reviewed: 12/04/2019 Date of next review: 12/04/2021

Written By	Signature	Date
Hazel Burt		12/04/19
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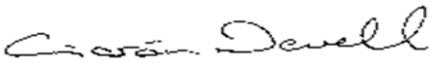
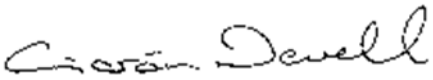
Dr Ciarán Newell		12/04/19
Authorised By	Signature	Date
Dr Ciarán Newell		12/04/19