Dorset HealthCare University NHS Foundation Trust

Standard Operating Procedure for Site Closedown

Objectives	The purpose of this SOP is to describe the procedure for the study close-down at Dorset HealthCare (DHC), detailing the process and the essential documentation required.
Scope	This procedure is applicable to all research study personnel in DHC.
Responsibility	The Principal Investigator is responsible for informing all members of the study team and all applicable review bodies of the study closure.
Related Document	Archiving SOP.

1 Purpose

The purpose of this Standard Operating Procedure is to describe the procedure for closing down a research study at DHC.

2 Introduction

According to ICH GCP the close-down of a clinical trial can only be done when both the investigator/institution site files, and the sponsor files have been reviewed and it has been confirmed that all necessary documentation pertaining to the trial have been completed. ICH GCP Guidelines define the study documents to be filed after completion or termination of the trial. This is an essential process.

3 Training

New users must read and understand this SOP before carrying out this procedure. Existing users must read and understand the Revisions Section.

4 Revisions

This is the second version of this SOP.

5 Procedure

The Research Ethics Committee (REC) which gave a favourable opinion of the research must be notified of its conclusion, in writing using the appropriate Declaration of the End of a Study form from the Chief Investigator within 90 days of the study closure or within 15 days if the study was terminated early.

As soon as the PI or any study personnel are informed of study closure, the research team will ensure that all data required by the protocol are recorded, all essential documents are and a copy of the Declaration of the End of a Study form should be filed. The study team will meet to finalise the closure of the study and to confirm that all study-related activities have stopped.

The PI or delegate is to ensure that all data queries have been completed and any equipment loaned/provided by the sponsor have been returned.

The study team need to notify the R&D office who will then:

- Update the study status
- Ensure any Honorary Contracts or Letters of Access are terminated
- Ensure any Monitor access is removed from the Electronic Medical Records (EMR)
- Ensure all finance is up-to-date

All essential documents will be retained for at least 15 years after completion unless otherwise specified in the study protocol.

A member of the research team will inform pharmacy and other support departments of the study closure. It is the responsibility of each service support department to ensure they close-down in accordance to the study's procedure and forward any files/documents to R&D for archiving.

The research team should send a copy of the formal notification of study closure received from the sponsor to the R&D office.

Once R&D has received the Sponsor's notification of study closure and the NRES Declaration of the End of a Study form, they will close the study on the R&D database.

6 Appendices

There are no appendices associated with this SOP.

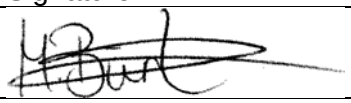
7 Responsibilities

The Principal Investigator is responsible for informing all members of the study team and all applicable review bodies of the study closure. The Research & Development team are responsible for ensuring all documentation is up to date ready for the study closure.

8 Review

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

Date reviewed: 12/04/19 Date of next review: 12/04/21

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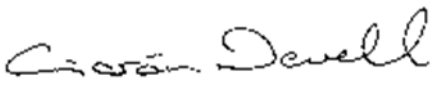
Dr Ciarán Newell		12/04/19
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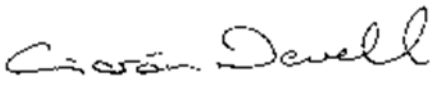
Dr Ciarán Newell		12/04/19