

SOP 850 Clinical Data Management System: CLOSEDOWN

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
Division responsible for document:	Research & Development
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2. Definitions of Terms Used / Glossary

CDMS	Clinical Data Management System
CI	Chief Investigator
CTU	Clinical Trials Unit
DBM	Database Manager
GCP	Good Clinical Practice
ICH	International Conference for Harmonisation
NNUH	Norfolk and Norwich University Hospital
PI	Principal Investigator
R&D	Research and Development
SM	Study Manager
SOP	Standard Operating Procedure
SVP	System Validation Plan
TT	Tools and Templates
UEA	University of East Anglia

3. Objectives

The objective of the process laid out in this SOP is to ensure the appropriate and effective close down of the Clinical Data Management System (CDMS) at the end of a trial.

4. Scope

This SOP applies to all research managed by Norwich CTU however the principles contained in this SOP shall be followed for all other trials.

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5. Purpose

The purpose of this SOP is to describe the process of closing down the CDMS at the end of a trial.

6. Rules

Before Closedown the trial database must be in a LOCKED state

If it is not in a locked state, the CI / PI or SM must request a database lock following the - Lock procedure **SOP 815 Clinical Data Management System – LOCKING AND UNLOCKING THE DATABASE.**

7. Closedown Procedure



- The SM must complete a Closedown Request form, based on an agreed template; refer to **SOP 825 Clinical Data Management System – VALIDATION.**



- The DBM will arrange to take a final backup of the database and export all the data to a comma separated value text file (.csv).
- These files will be put onto appropriate media and a copy sent securely to the CI/PI.
- A copy will also be held in storage by the Data Management Team for the requisite period (noted in the trials Data Management Plan). The media should be marked clearly with the earliest disposal date.



- If required and funding is available, filtered/localized datasets will be sent to the PI at each Study Site.





- A restricted copy of the database is kept online until the Data Management Team are requested to archive.
- The CI (or delegate) will notify the Data Management Team when archival is to be initiated, this cannot happen until at least a year after the publication of papers arising from the study.
- The Norwich CTU Data Management Team follow the working instruction on formal archiving.

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8. References and Related SOPs

References	
Norwich CTU Data Management Team working instruction on formal archiving	
SOP No.	SOP Title
SOP 815	Clinical Data Management System – LOCKING AND UNLOCKING THE DATABASE
SOP 825	Clinical Data Management System - VALIDATION

9. Approval

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10. Training Implication

Training Implication	
Actions required	<ul style="list-style-type: none"> Review SOP