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SOP 815 Clinical Data Management System – LOCKING AND UNLOCKING THE DATABASE

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
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1. Contents

2. Definitions of Terms Used / Glossary

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

3. Objectives

The purpose of database locking is to provide a stable base for interim or final analysis. The authorisation and validation process for locking and unlocking the database will ensure that the database is in a known good state at the end of the study.

4. Scope

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

5. Purpose

This SOP describes the standard procedures for locking and unlocking the database associated with Clinical Trials and a Clinical Data Management System.

6. Rules

DATABASE LOCKING

- Is the process of removing the ability of users to add, edit or delete data.
- May be partial (leaving certain areas of the database open for further edits) or full (no changes allowed).
- Partial locking may be useful towards the end of the study to allow verification and 'cleaning' of sections of the database where data entry has finished, leaving other areas open for data entry to continue.

DATA VALIDATION

- There must be a Study Data Validation Plan which lists all the checks that will be made post-lock to ensure that the dataset is in as good a state as possible.
- The Data Validation Plan must be executed on the database each time it is locked. Any checks arising should be resolved or accepted and documented by the study statistician. Details of the checks (e.g. database query code) should be retained so that they can also be re-run once the database has been re-locked after resolution.
- Refer to **SOP 730 Computer System Validation** and **SOP 825 CDMS – VALIDATION** for further information.

DATABASE STATUS

The Data Management Team must keep a record of the database status which may be one of the following:

- LIVE
- PARTIALLY LOCKED
- LOCKED and AWAITING VALIDATION
- LOCKED and VALIDATED

7. Procedure

7.1 Locking the Database

- A database lock must be requested by the SM, using a database lock request form based on an agreed template. (**SOP 825 CDMS – VALIDATION**)
- The form must be completed, signed and submitted to the DBM who will arrange to lock the database at the requested time.

- On receipt of the Database Lock Request form the DBM will take the necessary steps to ensure that access to all users will be restricted to read-only.

- A full backup of the database will be taken and stored in the DM team study folder.

- The Data Management Team will record the status of the database as LOCKED and UNVALIDATED

7.2 Validate the Database

- On locking the database, the DBM must run the queries, as specified in the Data Validation Plan to check for missing, invalid, or inconsistent data.

- Any validation failures must be submitted to the SM and/or the Study Statistician for agreement about resolution or otherwise.
- Appropriate actions for validation failures could be to unlock the database for corrections to be made, or acceptance of minor errors (to be listed in a report and signed by the CI/PI).

- When the database has been declared 'Validated', datasets for analysis may be requested by the study team, using a Data Request Form (**SOP 825 CDMS – VALIDATION**) based on an agreed template.

- The Data Management Team will record the status of the database as LOCKED and VALIDATED

7.3 Making a Locked copy of the Database for Interim Analysis

- When data is required for interim analysis, a locked and validated dataset must be produced.
- Disruption to the live ongoing study database must be kept to a minimum.

- The requester must complete a Dataset request form and ensure that it indicates that the request is for an **interim analysis dataset**.

- The DBM will make a copy of the live database and name it <StudyName>_Interim

- The standard locking and validation process should then be run on the Interim database copy.

- Corrections to any validation errors must first be made in the <StudyName>_Interim database and then must also be applied to the live database at the discretion of the CI/PI and the DBM.

7.4 Unlocking the Database

- There may be a need for the database to be unlocked if correction of validation errors is required.

- The CI/PI must complete a Database unlock request form, based on an agreed template, and submit it to the DBM.

- The DBM will set up access rights as required for the Study Team to make the necessary amendments.

- The Data Management Team will record the status of the database as PARTIALLY LOCKED

8. References and Related Documents

References
Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice (E6R2), Step 4 version, dated 9 November 2016
Template Database Lock Request Form
Template Data Request Form

SOP No.	SOP Title
SOP 325	Start-up activities for a clinical trial
SOP 730	Computer System Validation
SOP 815	Clinical Data Management System – LOCKING AND UNLOCKING THE DATABASE
SOP 860	Clinical Data Management System - DATA REQUEST
SOP 825	Clinical Data Management System - VALIDATION

9. Approval

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10. Training Implication

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