STU-SOP-DMS-010 – Standard Operating Procedure on Data Locking and Release

Version No:	5	**Effective Date:**	27-Mar-2026
Description of changes:	SOP reviewed in light of clinical trial regulations 2025 and GCP updates. Specific references to QPulse as the QMS have been removed. We now only refer to a QMS system. Removal of the term “freeze”.		

List of Abbreviations	
CI	Chief Investigator
DM	Data Manager
DMC	Data Monitoring Committee
GCP	Good Clinical Practice
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
SU	Swansea University
TM	Trial Manager
TMF	Trial Master File
TMG	Trial Management Group
TS	Trial Statistician

1. Purpose and Definitions

This Standard Operating Procedure (SOP) describes the procedure of data freezing, locking, and release for analysis as well as procedures to update data after a freeze or lock.

Definitions	
Form lock	A process used by the Data Manager prevent further edits to specific case report forms without their knowledge. This is an administrative task usually following central monitoring and may happen numerous times prior to record lock and database lock
Record lock	A process used by the Data Manager to prevent further edits to specific patient records without their knowledge. This is an administrative task, usually conducted following that patient’s last visit once all individual forms are locked, and may happen numerous times prior to database lock.
Database Lock	When there is no expectation for data to change and declares data ready for analysis. In a locked state no further changes can be made to the live/main dataset without prior approval and access being granted.
Snapshot data extract	An extract of the database as it was at a specified point in time. A snapshot data extract might constitute a back-up of the database, or might be used for central monitoring or data management processes set out in the study Data Management Plan.
Interim data release	An extract of the database at a specific time provided ‘as is’ for interim analysis, review by oversight committees or other relevant purposes
Final data release	The process of providing data for analysis and archiving after the data have been locked.

2. Background

It is a requirement of Good Clinical Practice (GCP) that data are "recorded, handled and stored in a way that allows accurate reporting, interpretation and verification." Locking data are defined processes required to finalise data and prevent subsequent unauthorised changes.

A database lock will normally be requested following the end of a project, once all data collection and project related data activities have been completed and all forms and records have been locked. Interim analyses may be required, in which case the process for, locking and release of the data for this snapshot review will be followed.

3. Roles and Responsibilities

The **Chief Investigator (CI)** is responsible for authorising data lock or unlock. This is usually completed in consultation with the Data Manager (DM) and Trial Statistician (TS). The CI also has responsibility for notifying the Trial Management Group (TMG) that a data lock/unlock has occurred (this may be delegated to the TM).

The **Trial Management Group (TMG)** is usually responsible for overseeing and monitoring the locking and unlocking of a database and data release and agreeing on a presentation of the data that does not inadvertently unblind.

The **Data Manager (DM)** is responsible for locking, unlocking and releasing data as set out in the data management plan.

The **Trial Statistician (TS)** or delegate is responsible for requesting a database unlock where necessary.

External use of SOP: This SOP and Associated Documents (AD) may be used for research projects not adopted by Swansea Trials Unit (STU) where Swansea University (SU) staff and associated NHS organisations require guidance. In such instances, oversight responsibility for any associated tasks will not be the responsibility of STU.

4. Procedure

4.1 Form lock and record lock

For some projects, it may be possible for individual data entry forms or participant records to be locked by the DM. This should follow routine data quality checks (per the data management plan) when the DM is satisfied the data is complete, accurate and all data queries are resolved. This requires no prior approval and is at the discretion of the DM to prevent data changes when fields and forms have undergone quality checks. Users can still access the entire database and edit unlocked forms/records.

4.2 Form unlock and Record Unlock data

Forms and records may be unlocked if further data queries or edits are needed. The DM will remove the restrictions and inform the appropriate site(s). Once the queries are resolved or the updates are made, the DM will revalidate the data and reinstate the form lock and/or record lock.

4.3 Database Lock

Once all data entry is complete, final data validation has occurred (per STU-SOP-DMS-008 Data Management), and all forms and records have been locked, the project database may be locked on receipt of a valid Database Lock Request Form (STU-AD-FRM-025).

The method used will depend on the Clinical Data Management System in use, but will ensure all rights to edit data shall be revoked, and the database cannot be changed without the knowledge of the DM. The TMG shall be informed that data have been locked. The authorised data locking form and evidence that all data related research project activities are complete must be stored in the Trial Master File (TMF).

4.4 Unlocking data

A Database Unlocking Request Form (STU-AD-FRM-026) must be completed to gain approval to unlock. Appropriate data editing permissions will be restored, and the specific forms and records to be changed will be unlocked.

Once queries are resolved, the DM will validate that only changes specified in the Database Unlocking Request Form have been made, and relock those forms, records, and the database following the process above.

Any parties provided with a copy of the data must be notified of the changes and provided with an amended version as required.

4.5 Data Release

Formal data releases, including interim data releases, are usually agreed by the TMG. Snapshot data extracts for the purposes of central monitoring, reporting to trial groups, backing up the database, or other processes set out in the Data Management Plan would not normally require prior agreement by the TMG.

Only data from a locked database may be released for final analysis. Requirements for interim analysis will be set out in the research project protocol. Additional requests for data release e.g. by a DMC may occur and would normally require prior agreement by the TMG.

Where a completed Data Release Request Form (STU-AD-FRM-027) is received, an export of the relevant data will be released in an agreed format. This will be saved in a secure folder and should clearly specify the date and time exported. If the recipient is blinded, the data file must be in accordance with STU-SOP-DMS-002 (Blinding and Unblinding) to ensure that it maintains the blind as far as possible. All requests and approvals for data must be stored in the TMF.

5. References

- Medicine and Healthcare products Regulatory Agency website (MHRA) - https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/services-information
- UK policy framework for health and social care research (2017) - https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
- UK Medicine for Human Use (Clinical Trials) Regulations 2025 - https://www.legislation.gov.uk/uksi/2025/538/contents

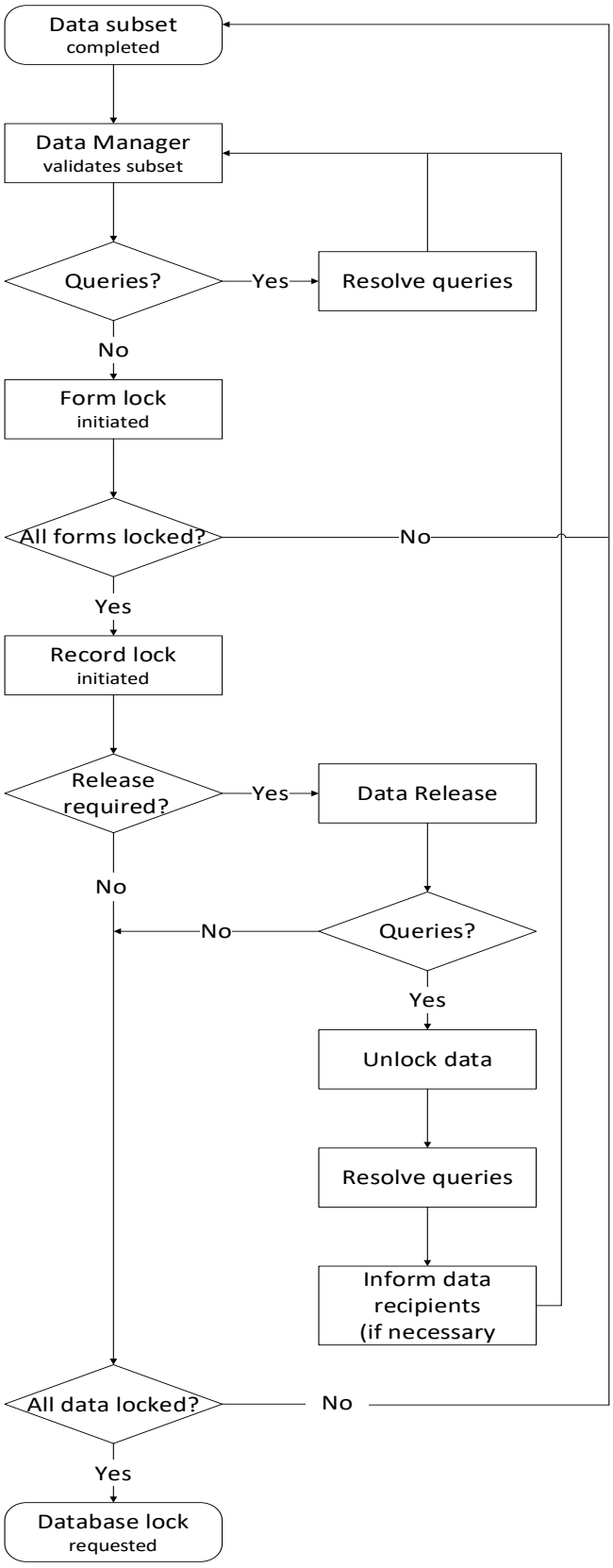
It is assumed that by referencing the principal regulations that all subsequent amendments are included in this citation.

6. Associated Documents

Number	Title	Location
STU-AD-FRM-025	Data Lock Request Form	QMS
STU-AD-FRM-026	Data Unlocking Request Form	QMS

7. Appendices

Appendix 1: Record lock/unlock and form lock/unlock



Appendix 2: Locking and Unlocking Data