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

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	
Freeze	The process used by the Data Manager following central monitoring to prevent further data edits without their knowledge. This is an administrative task that may happen numerous times prior to data lock.
Snapshot data release	An extract of the database as it was at a specified point in time. The extract from this point in time is classed as a copy of the data fixed at the time of extraction.
Lock	The stage after freeze, 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.
Final data release	The process of providing data for statistical analysis 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." Freezing and locking data are defined processes required to finalise data and prevent subsequent unauthorised changes.

A data 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 data have been frozen. There may be a snapshot release/interim analyses required, in which case the process for freeze, lock 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), Trial Manager (TM) and Trial Statistician (TS). The CI also has responsibility for notifying the 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 unlocking of a dataset and data release, and agreeing on a presentation of the data that does not inadvertently unblind.

The **Trial Manager (TM)** is delegated responsibility for coordinating the data lock/unlock process for the research team.

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

The **Trial Statistician (TS)** or delegate is responsible for requesting a data 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 Freezing Data (see Appendix 1)

For some project, it may be possible for individual data entry forms to be frozen by the DM. This feature should be used following 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 form freeze 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.

Once all data entry is complete and the final data validation has occurred (per STU-SOP-DMS-008 Data Management), the project data may all be frozen. The method used will depend on the Clinical Data Management System in use ensuring data across the entire database cannot be changed without the knowledge of the DM.

A final data freeze applies to all data within the database and is intended as a final step before data locking.

4.2 Unfreezing data (see Appendix 2)

Data may be unfrozen if further 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 data freeze.

4.3 Locking Data (see Appendix 3)

On receiving a valid Data Lock Request Form (STU-AD-FRM-025), all rights to edit data will be revoked. 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 (see Appendix 3)

A Data Unlocking Request Form (STU-AD-FRM-026) must be completed to gain approval to unlock. Data editing permissions will be restored.

Once queries are resolved, the DM will lock the data 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

Data release, which may be a snapshot is usually agreed by the TMG. A data release is normally requested for central statistical monitoring purposes, Data Monitoring Committee (DMC) reporting or data analysis.

Only locked data may be released for final report analysis. Requirements for snapshots and interim analysis, will be set out in the research project protocol. Additional requests for data release e.g. by a DMC may occur.

Where a completed Data Release Request Form (STU-AD-FRM-027) is received, an export snapshot 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

- Health Research Authority website (HRA) - http://www.hra.nhs.uk/
- 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 2004 - http://www.legislation.gov.uk/uksi/2004/1031/contents/made

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	Q-Pulse
STU-AD-FRM-026	Data Unlocking Request Form	Q-Pulse
STU-AD-FRM-027	Data Release Request Form	Q-Pulse

7. Abbreviations

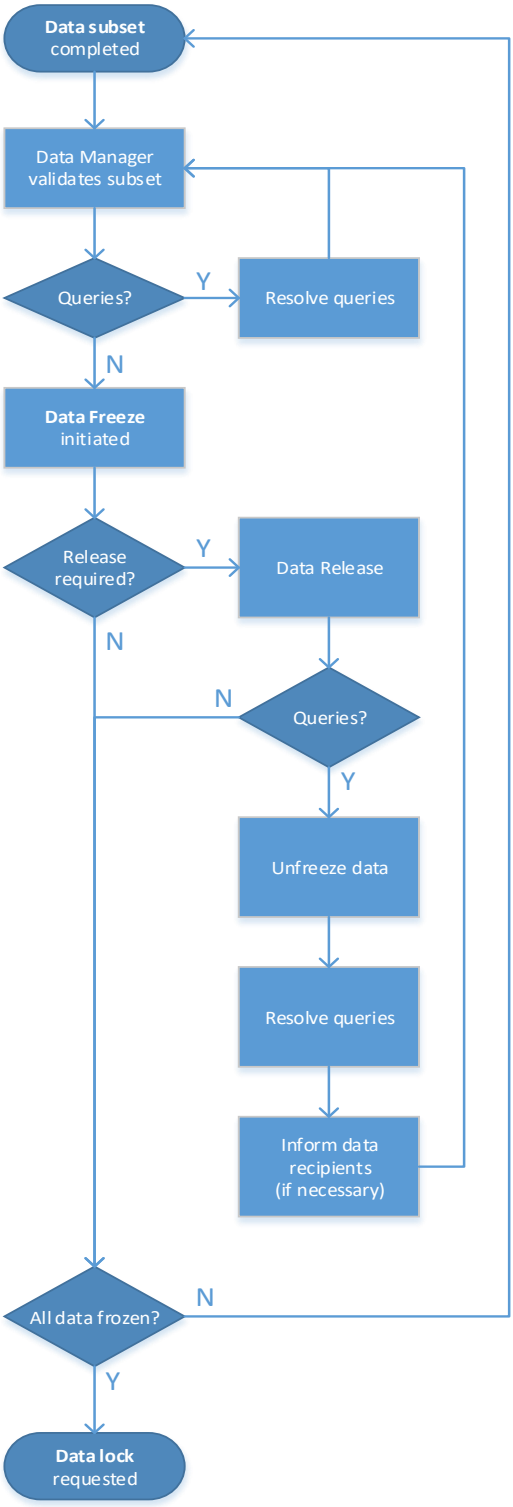
List of Abbreviations	
CI	Chief Investigator
DM	Data Manager
DMC	Data Monitoring Committee
GCP	Good Clinical Practice
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
SU	Swansea University
TM	Trial Manager
TMF	Trial Master File
TMG	Trial Management Group
TS	Trial Statistician

8. Appendices

Appendix 1: Document History

Version No:	4	**Effective Date:**	26-Mar-2024
Description of changes:	Clarification of data freeze procedure Update to SOP template v5		

Appendix 2: Freezing and Unfreezing Data



Appendix 3: Freezing and Unfreezing Data