STANDARD OPERATING PROCEDURE FOR LOCKING CLINICAL STUDY DATABASES

SOP NUMBER:	TASC SOP032 v8
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ISSUE DATE:	25 Mar 2023
EFFECTIVE DATE:	25 Mar 2023
REVIEW DATE:	25 Mar 2025

1. PURPOSE

This SOP describes the process for locking data in a clinical study database in accordance with the principles of Good Clinical Practice.

2. SCOPE

This document applies to Clinical Trials of Investigational Medicinal Products and is recommended for other clinical research studies sponsored or co-sponsored by the University of Dundee and/or NHS Tayside.

This SOP should be read in conjunction with the Study Lock Checklist (Doc Ref 105).

This Standard Operating Procedure (SOP) is intended for use by those involved with the management of data in clinical research studies

3. RESPONSIBILITIES

Chief Investigator (CI):

- All data queries/discrepancies are resolved.
- Serious Adverse Events (SAE) have been reconciled with TASC Pharmacovigilance team.
- Data has been quality checked.
- Pre-lock meeting held to gain approval for database lock.
- Meeting documented and study lock checklist completed.
- Database user permissions removed or set to read only.
- Randomisation codes (if relevant) and data for analysis transferred securely to person(s) responsible for analysis.

4. PROCEDURE

4.1 After completion of data entry, a clinical study database will be locked to prevent further additions and/or changes to the data. Database lock will be carried out following any import of external data to the database, resolution/closure of all discrepancies and reconciliation with external systems. Locking of data may be for a whole study or an agreed part of a study, such as a site in a multi-centre study. Final database lock will be

performed prior to unblinding of data, final data extraction and main analysis of data.

4.2 When all applicable data have been entered into the clinical study database, all data queries and discrepancies have been closed, SAEs have been reconciled with the sponsor's pharmacovigilance database and quality checks have been carried out, a database pre-lock meeting will be convened.

4.3 Attendees at the database pre-lock meeting will include those responsible for Trial Management, Data Management and data analysis, as well as a clinical investigator, preferably the CI. At a minimum, the CI and the Statistician should authorise the database lock. Documentation will be filed in the Trial Master File (TMF).

4.4 A checklist of items (based on the Doc Ref 105 Study Lock Checklist) will be reviewed at the database pre-lock meeting and the proceedings of the meeting documented.

4.5 If all items documented in the Study Lock Checklist (Doc Ref 105) are approved at the meeting, permission may be given to proceed to final lock of the database. If approval is not given, issues identified will be addressed and a final approval to lock obtained later and documented.

4.6 When permission is given for final database lock, user permissions will be restricted to read only (if the system supports this) or removed. Access should only be retained by limited personnel for administrative purposes. The study data will be put into a state such that further additions or changes to the data are not possible, i.e. locked.

4.7 An email will be sent to relevant parties to confirm that the clinical study database has been locked.

4.8 For blinded studies the release of randomisation codes will be requested after data lock.

4.9 Data extracted after the lock will be transferred, using standard practices, to the person responsible for data analysis.

4.10 A record of the steps taken in the locking process, release of data and requesting of unblinding codes will be documented and filed in the TMF.

4.11 If errors with a significant impact on analysis, safety or efficacy are found following database lock, the CI, Sponsor and those responsible for Trial Management, Data Management and data analysis will discuss and document procedures to be followed that will allow the necessary changes to the data to be undertaken, including unlocking the database (authorised by the Sponsor), bearing in mind the implications for integrity of the study data. If the system has no built-in audit trail, both the original database and the corrected database will be retained and subsequently archived. Re-locking the database will follow the same procedure as the initial lock.

4.12 If changes are made subsequent to any publication from the original results, the corrected database and a copy of the preceding locked database will be archived and recorded in the archived studies log, with reference to the publication.

5. ABBREVIATIONS

CI	Chief Investigator
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre

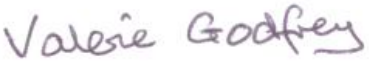
6. ASSOCIATED DOCUMENTS & REFERENCES

Doc Ref 105: Study Lock Checklist

7. DOCUMENT HISTORY

Version Number:	Reviewed By (Job Title)	Effective Date:	Details of editions made:
History of reviewers prior to 2019 is detailed in the archived SOPs			
5	Emma McKenzie (Clinical Trial Information Systems Manager	26/03/2019	Refreshment of text for clarity of process. New TASC SOP format implemented.
6	Tracy Petrie (Quality Assurance Support Officer)	29/01/2021	Uploaded to new TASC SOP template which shows the new TASC website in the footer. Physical scan converted to electronic pdf as a requirement for upload to new TASC website.
7	Eva Lahnsteiner (Data Manager)	25/03/2021	Refreshment of text for clarity of process and update to numbering.
8	Marcus Achison (Database Manager) Andrew McKenzie (SAS Programmer)	25/03/2023	Minor changes to text.

8. APPROVALS

Sign		Date
APPROVED BY:	Professor Russell Petty, R&D Director, NHS Tayside	
Signature		17 March 2023
APPROVED BY:	Dr Valerie Godfrey, TASC QA Manager, Chair of Clinical Research Guidelines Committee	
Signature		15 Mar 2023