ECTU Central Office SOP ECTU_OP_20: Requests to Lock and Unlock a Study Database

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Authorship and Approval			
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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	27 Nov 2023	Initial creation
2.0	02 Nov 2026	Clarification added to the Scope that interim and progressive final analyses are not included in this SOP. Former Section 4.2, split into “4.2 Error(s) identified on a locked database” and 4.3 “Unlocking and relocking a previously locked database” to further clarify process. New section added: “4.4 Partial Locking of a Database”. Overall wording streamlined to avoid repetition.

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the process for formal locking of the study database. It covers formal end of study database locking in a clinical study database in accordance with the principles of Good Clinical Practice (GCP). Final lock will be carried out prior to final data extraction, and final analysis of data. This SOP also covers partial locking of data.

2.0 SCOPE

This SOP applies to Clinical Trials of Investigational Medicinal Products (CTIMPS) whether full or partial collaboration studies and is for clinical research trials where databases are held within the Edinburgh Clinical Trials Unit (ECTU) or managed by ECTU but hosted elsewhere (e.g., trusted research environments). It is recommended that this is also followed for nonregulated projects, where possible.

This SOP is for those within ECTU who are involved with the management of data, including Trial Management, Data management, Statisticians and Health Economists when these tasks have been delegated to ECTU.

Creating and securing snapshots of study data, whereby a fixed version of the data is preserved at a specified time point for analysis without formally locking the entire database, for example for interim analyses or progressive final analyses, such as those conducted in platform trials, is outside the scope of this SOP.

3.0 RESPONSIBILITIES

The Trial Statistician (or designee) is responsible for formally requesting that database is locked/unlocked as appropriate.

The ECTU Data Management and Programming (DM&P) Team is responsible for providing a data cleaning plan, including timescales. The team is also responsible for the database locking/unlocking process and ensuring this is documented. The DM component of the team handles databases hosted in REDCap, while the Programming component manages bespoke databases hosted in SQL.

The Trial Manager (TM) (or designee) ensures the study teams are informed of the timelines involved. The Trial Manager coordinates with responsible teams for the completion of the ECTU Study Database Lock Checklist (OP-F04). If there is no ECTU Trial Manager, the ECTU Business Coordinator or Designee will be responsible, as appropriate.

4.0 PROCEDURE

For all activities described in this SOP, any evidence generated must be stored in the Trial Master File (TMF). If the TMF is held externally, documentation may be maintained within the relevant sections of DataStore and shared with the external trial manager for filing, either contemporaneous or at the time of archive. Emails forming part of the evidence trail must be saved as PDF files and stored in the appropriate TMF location. This applies to all applicable steps of this SOP unless an exception is explicitly stated.

4.1 Locking a database

4.1.1 There are several considerations and requirements needed to be carried out prior to database lock. "ECTU Study Database Lock Checklist" (OP-F04) should be completed by the Trial Manager/ ECTU Business Coordinator and used as guidance to ensure that all points are considered prior to database lock.

4.1.2 For ACCORD Sponsored studies, Safety Line listings should be requested from the Sponsor (safety@accord.scot) and Non-Compliance listings requested from Sponsor QA (QA@accord.scot). The general Monitors' email address (monitors@accord.scot) should also be copied in so as to provide oversight and any issues can be flagged at this point. For final analysis database lock, ensure that these are marked as 'Final'.

4.1.3 For non-ACCORD sponsored studies, the individual Sponsor's procedures around safety and non-compliance data should be followed, and the appropriate contact address for communication with the sponsor should be used. For studies that do not have an ECTU Trial Manager, this responsibility lies with the Business Coordinator (or designee).

4.1.4 All sponsor data that is requested under 4.1.2 and/or 4.1.3, and that is needed for statistical analysis, should be entered into or uploaded to the study database, if possible. If not possible, the reason, and a description of what was done should be given in the "ECTU Study Database Lock Checklist" (OP-F04), however, this data must subsequently be included in the statistical analysis dataset.

4.1.5 Once the "ECTU Study Database Lock Checklist" (OP-F04) has been completed and the trial statistician (or designee) is satisfied that the study database can be locked (as per ECTU_WPD_ST_W5: Statistical Analysis and Reporting), the trial statistician (or designee) will notify (where applicable), the study sponsor (e.g. via email) of the intention to lock the database. For ACCORD-sponsored studies, the email should be sent to resgov@accord.scot, with the Sponsor Monitors (monitors@accord.scot) copied in. The email should state that ECTU are ready to lock the database. Once confirmation to proceed with the database lock has been received from the sponsor, the trial statistician (or designee) will request (e.g. via email), that the DM&P Team lock the database, where applicable, the trial in-box or the Business Coordinator, Chief Investigator (CI) and Sponsor will be copied in this request.

4.1.6 The completed "ECTU Study Database Lock Checklist" (OP-F04) and associated email correspondence to the Sponsor should be filed.

4.1.7 Once the DM&P Team have received the email requesting to lock the database, the database will be locked as per the DM&P procedures. For bespoke databases, the programmer/developer will follow ECTU SOP IT 24. For REDCap databases, the steps in REDCap SOP 07 should be followed.

4.1.8 The locked data will be in a state where no further additions, deletions, or changes can be made.

4.1.9 An email will be sent from the designated DM&P team member to the trial in-box or the Business Coordinator, the trial statistician (or designee) and the CI, to confirm that the database has been locked.

4.2 Error(s) identified on a locked database

4.2.1 If an error(s) that might have a significant impact (for example, an error affecting the primary endpoint or key secondary endpoints) is identified following database lock, the person identifying the error(s) should raise it, with the CI, trial statistician, trial manager and any other relevant stakeholders (for example, the Sponsor).

4.2.2 The relevant trial team members and stakeholders should assess the significance of the error(s), its potential impact on the integrity of the study data and (where applicable) on any analyses or reports already produced, and agree the appropriate course of action. A description of the error(s), the significance assessment, and the agreed actions should be documented in a file note (OP-T06). This assessment will have one of two possible outcomes:

- If the error is deemed not significant, no further action is required.
- If the error is deemed significant, a database unlock and subsequent relock may be required as per section 4.3 of this SOP. Where an unlock/relock is required, the file note should also document the reason for the database unlock, a specific list of required changes, and the individual(s) responsible for making and verifying the changes.

4.3 Unlocking and relocking a previously locked database

4.3.1 This process applies where an error has been deemed significant in accordance with Section 4.2 and a database unlock is required.

4.3.2 If the Final Statistical Analysis Report has already been issued, the file note should also include a list of individuals and/or organisations that need to be informed of the error(s), and any resulting changes. Depending on the timing and nature of the changes, these may include the Sponsor, Trial Steering Committee, relevant Data Sharing Committee, study participants, relevant reporting portals and/or journals containing associated publications. This task would be completed by a nominated designee according to the applicable requirements at the time.

4.3.3 Approval to unlock the trial database will be provided by the trial statistician (or designee) to the DM&P team via email. The CI and TM should be copied into the email. The TM, or Business Coordinator when there is no ECTU TM, will forward the email to the relevant Sponsor contact.

4.3.4 Once the DM&P team have received the approval email to unlock the database, the database will be unlocked. Only those individuals required to implement the required changes specified in the file note should be granted access to the database.

4.3.5 An email will be sent from the DM&P team to relevant individuals (trial in-box (if applicable), trial statistician (or designee) & CI) to confirm that database has been unlocked.

4.3.6 Once the database is unlocked, only the specified changes in the file note should be made. The database should be relocked as soon as reasonably appropriate to prevent other data changes being made.

4.3.7 When the database is relocked, the audit trail for that database should be reviewed to confirm that only the required changes have been made. This check should be carried out by the DM&P team and should be documented and stored.

4.3.8 Relocking the database should follow the same procedure as the initial lock, from 4.1.5 to 4.1.9 (although there may be no requirement to complete a new ECTU Study Database Lock Checklist (OP-F04)).

4.4 Partial locking of a database

4.4.1 Certain studies may require partial database locks, meaning that only specific areas of the database are going to be locked. This may be required, for example, where the study is conducted in stages, such as a pilot and then a main phase, or where an adaptive design is used in which certain arms are closed to recruitment. The affected areas of the database should be checked and cleaned before being locked. Once locked, the data will be in a state where no further additions, deletions, or changes can be made, as described in 4.1.8 of this SOP.

4.4.2 This should be documented using "ECTU Study Database Lock Checklist" (OP-F04). The applicability of steps 4.1.2 to 4.1.4 of this SOP should be considered on a case-by-case basis, taking into account the purpose and scope of the partial database lock. These activities may be required, for example, where a treatment arm is being discontinued, but may not be necessary for other types of partial database lock. Where applicable, ensure that the relevant entries are marked as 'Partial' and include a timestamp, for example, 'Partial_DDMMMYYYY'.

4.4.3 Once the "ECTU Study Database Lock Checklist" (OP-F04) has been completed for the partial lock, the process can continue as described in 4.1.5 to 4.1.9. Where a previously partially locked area of the database needs to be unlocked and subsequently relocked, the process described in 4.2 and 4.3, should also be followed.

5.0 RELEVANT DOCUMENTS AND REFERENCES

ECTU Website

- ECTU SOP TM 14 End of Trial Notification and Trial Close-Out
- ECTU SOP IT 24 Database Lock
- ECTU SOP REDCap 07 Project Lock - Total Database Lock
- ECTU WPD ST W5 Statistical Analysis and Reporting
- OP-F04 ECTU Study Database Lock Checklist

- OP T06 File Note Template

ECTU_SOP_OP_20 Requests to Lock and Unlock a Study Database v2.0 and associated document

Final Audit Report 2026-09-29

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Document created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
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