

## 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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Kenton D'Mellow, Data Management Team Lead	Reviewer	13 Nov 2023	See retained email approval dated 13 Nov 2023
Gina Cranswick, Trial Management Team Lead	Approver	06 Nov 2023	See retained email approval dated 06 Nov 2023
Tanya Tharakan, QA Manager	QA Authorisation	07 Nov 2023	See retained email approval dated 07 Nov 2023

Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	27 Nov 2023	Initial creation

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## 1.0 PURPOSE

This 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, for instance prior to interim analysis.

## 2.0 SCOPE

This SOP applies to Clinical Trials of Investigational Medicinal Products (CTIMPS) and is for clinical research trials where databases are held within ECTU. 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.

## 3.0 RESPONSIBILITIES

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

The ECTU Data Management (DM) Team are responsible for providing a data cleaning plan, including timescales. They are responsible for the database locking/unlocking process and ensuring this is documented.

The Trial Manager (TM) ensures the study teams are informed of the time lines involved. The Trial Manager coordinates with responsible teams for the completion of the database lock checklist. If there is no ECTU Trial Manager, the ECTU Business Coordinator or Designee will be responsible, as appropriate.

## 4.0 PROCEDURE

### 4.1 Locking a database

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](mailto:safety@accord.scot)) and Non-Compliance listings requested from Sponsor QA ([QA@accord.scot](mailto:QA@accord.scot)). The general Monitors' email address ([monitors@accord.scot](mailto: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'. For other types of database lock, Safety line listings should be requested as necessary, and will be updated in the ECTU

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Study Database Lock Checklist' (OP-FX04, overseen by either by Statistician or Data Manager, depending on the project

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 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 – the data must be included in the statistical analysis dataset.

4.1.5 Once the ECTU Study Database Lock Checklist has been completed and the trial statistician is happy to lock the study database, approval to lock the database will be provided by the trial statistician (or designee). The trial statistician (or designee) should inform the DM Team, Trial Manager, CI and Sponsor by email. For ACCORD-sponsored studies the email address is ([regove@accord.scot](mailto:regove@accord.scot)), and the Sponsor Monitors ([monitors@accord.scot](mailto:monitors@accord.scot)) should be copied in. The email should state that ECTU are ready to lock the database.

4.1.6 The completed checklist and email correspondence to the Sponsor should be filed in the trial master file (TMF). When the TMF is held externally these should be stored in the Statistical Master File subsection of the TMF.

4.1.7 Once the DM team have received the approval email to lock the database, the database will be locked as per the DM procedure. For bespoke databases, the 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 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 database has been locked. This confirmation email should be retained in the TMF and can be held in the Statistical Master File subsection of the TMF when the TMF is held externally.

## **4.2 Unlocking and relocking a previously locked database**

4.2.1 If errors with significant impact on analysis, safety or efficacy are found following database lock, the CI, Sponsor, and those responsible for trial/data management and data analysis will discuss and document the procedures to be followed that will allow the necessary changes to be undertaken, including unlocking databases. Consideration should be made for the implications on the integrity of the study data.

4.2.2 The reason for the unlock request, and the decision, should be documented, along with a specific list of required changes, and the individual(s) who will make them. If the Final Statistical Analysis Report has already been dispatched, the documentation should contain a list of people who need to be informed of the alteration (such as the Sponsor, Trial Steering Committee, Study Participants, reporting portals, journal containing publication) – the precise list will depend on the timing of the decision in relation to the reporting process. This task

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would be completed by a nominated designee according to the applicable requirements at the time. The documentation should be stored in the TMF and can be held in the Statistical Master File subsection of the TMF when the TMF is held externally.

4.2.3 Approval to unlock the trial database will be provided by the trial statistician (or designee) to DM team via email. This email should be stored in the TMF and can be held in the Statistical Master File subsection of the TMF when the TMF is held externally. The CI and TM should be copied in to the email. The TM, or Business Coordinator when there is no ECTU TM, will forward the email to the relevant Sponsor contact.

4.2.4 Once DM team have received the approval email to unlock the database, the database will be unlocked. Only those individuals required to implement the required changes should be granted access to the database.

4.2.5 An email will be sent from the DM team to relevant individuals (trial in-box (if applicable), trial statistician (or designee) & CI) to confirm that database has been unlocked. This confirmation email should be retained in the TMF and can be held in the Statistical Master File subsection of the TMF when the TMF is held externally.

4.2.6 Once the database is unlocked, only the pre-specified changes should be made. The database should be re-locked as soon as reasonably appropriate to prevent other data changes being made.

4.2.7 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 team and should be documented within the TMF and can be held in the Statistical Master File subsection of the TMF when the TMF is held externally.

4.2.8 Relocking the database should follow the same procedure as the initial lock, from 4.1.5 to 4.1.9 (although there is no requirement to complete a new Database Lock Checklist).

## 5.0 RELEVANT DOCUMENTS AND REFERENCES

- [ECTU SOP TM 14 End of Trial Notification and Trial Close-Out](#)
- ECTU SOP IT 24 Database Lock (On ECTU Shared Drive)
- ECTU SOP REDCap 07 Project Lock - Total Database Lock (On ECTU Shared Drive)
- [OP-F04 ECTU Study Database Lock Checklist](#)

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