

ECTU Central Office SOP_IT_24: Recording Requests for Database Lock or Unlock

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Effective Date:	11 Sep 2026

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Tanya Tharakan, QA Manager	QA Authorisation	27-Aug-2026	 Signature on file Tanya Tharakan (27-Aug-2026 16:17:41 GMT+1)

Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	10 Jun 2016	Initial creation/New document
2.0	22 May 2024	Document moved to v3 template. Extensive alterations throughout document. Added Responsibilities section; Updated with details of how to record the locking and unlocking of the study database. New database lock template reference added to section 5 (with proposed path).
3.0	11 Sep 2026	Update to sections 4.3 and 4.5 on the management of the Database Lock log.

The user of this document is responsible for ensuring it is the current version.

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the process of documenting the requests for database lock and/or unlock by the study statisticians or other appropriate designee.

2.0 SCOPE

This SOP applies to all University of Edinburgh staff employed within ECTU who are responsible for bespoke database systems.

3.0 RESPONSIBILITIES

The study Statistician (or designee) is responsible for:

- Requesting the database lock or unlock

The study Software Developer is responsible for:

- Creating the study database log
- Entering the details of lock/unlock request into the log
- Sending the email notification to the Trial mailbox, Study Statistician and CI.

4.0 PROCEDURE

- 4.1 Each time a request is made, typically by the study statistician, to lock and/or unlock the study, the Database Lock log should be updated to record the following details:
 - Name and designation of the requester. If the authority of the person making the request is uncertain, confirm with the Study Statistician before taking any action.
 - Type of Request – whether it is a Lock or Unlock
 - Brief description detailing the reason for the request, or other comments, if required.
 - Name of Software Developer implementing the request, the date and time it was implemented.
- 4.2 A log will be maintained for this purpose for each study using the Database Lock Log Template (see section 5). This log will be signed and dated by the Software Developer responsible for implementing the database lock or unlock.
- 4.3 The Database Lock Log must be completed and signed via Adobe after each lock and/or unlock request. The completed signed logs will be retained by the Software Developer in the Trial Master File, Section 9 for full-service study and section 3 for Partial service.
- 4.4 Detailed information on requests to lock and unlock a database can be found in ECTU_SOP_OP_20 Requests to Lock and Unlock a Study Database
- 4.5 An email will be sent to the Trial mailbox, Study Statistician, and CI, when the request has been completed. The Database Lock log will be included in the email notification to the requestor.

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5.0 RELEVANT DOCUMENTS AND REFERENCES

[On ECTU website:](#)

- ECTU_SOP_OP_20 Requests to Lock and Unlock a Study Database
- IT002 Database Lock Log Template

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ECTU_SOP_IT_24 Database Lock v3.0 and associated document

Final Audit Report

2026-08-27

Created:	2026-08-27 (British Summer Time)
By:	Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAAOaczMH5HnpSXGbZUQ7En9LNL35DD75yb

"ECTU_SOP_IT_24 Database Lock v3.0 and associated document" History

-  Document created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
2026-08-27 - 16:01:26 GMT+1- IP address: 192.41.114.230
-  Document emailed to Ronan Collins (ronan.collins@ed.ac.uk) for signature
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-  Email viewed by William Main (will.main@ed.ac.uk)
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2026-08-27 - 16:13:33 GMT+1- IP address: 104.47.11.254

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 Agreement completed.

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