
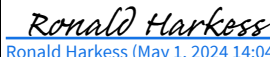




## ECTU Central Office SOP\_IT\_24: Recording Requests for Database Lock or Unlock

Version No:	2.0
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Effective Date:	22 May 2024

Authorship and Approval			
Name and Designation	Author/Reviewer /Approval/ Authorisation	Date	Signature
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Tanya Tharakan, QA Manager	QA Authorisation	06 May 2024	 Tanya Tharakan (May 6, 2024 11:51 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).

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 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 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.

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

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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

### **Database Lock Log Template** (on ECTU shared drive)

- Database Lock Log Template

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# ECTU\_SOP\_IT\_24 Database Lock v2.0


Final Audit Report

2024-05-06


Created:	2024-05-01 (British Summer Time)
By:	Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAAW1Rnx7xdc-31fLRcLlDAtImBFD_61FvH

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-  Document created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)  
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Signature Date: 2024-05-06 - 11:51:03 GMT+1 - Time Source: server- IP address: 185.241.227.253

 Agreement completed.

2024-05-06 - 11:51:03 GMT+1