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

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Authorship and Approval			
Name and Designation	Author/Reviewer /Approval/ Authorisation	Date	Signature
Tim Duncan, Senior Software Developer	Author	01 May 2024	Tim Duncan Tim Duncan (May 1, 2024 11:35 GMT+1)
Ronnie Harkness Senior Software Developer	Reviewer	01 May 2024	Ronald Harkess Ronald Harkess (May 1, 2024 14:04 GMT+1)
Kenton D'Mellow, Data Management & Programming Team Lead	Approver	05 May 2024	Kenton D'Mellow (May 5, 2024 11:13 GMT+1)
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).

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

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

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-31fLRCtLDAtlmBFD_61FvH

"ECTU_SOP_IT_24 Database Lock v2.0" History

Document created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
2024-05-01 - 10:55:14 GMT+1- IP address: 192.41.114.230

Document emailed to Tim Duncan (tim.duncan@ed.ac.uk) for signature
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