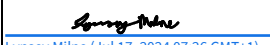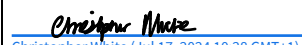# ECTU Central Office SOP ECTU_REDCap_07: Management of Study Database Lock and Unlock Requests

Version No:	4.0
Issue Date:	17 Jul 2024
Effective Date:	19 Aug 2024

Authorship and Approval			
Name and Designation	Author/Reviewer /Approval/ Authorisation	Date	Signature
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Tanya Tharakan, QA Manager	QA Authorisation	17-Jul-2024	*Tanya Tharakan (Jul 17, 2024 10:44 GMT+1)*

Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	25-Nov-2015	• Initial creation/new document
2.0	26-May-2016	• Change to name as REDCap allocated separate naming convention to IT
3.0	21-Nov-2016	• Change to name and scope for total database lock • Formatting and numbering altered and simplified for ease of use • Document and location added to section 4
4.0	19 Aug 2024	• Document moved to new template • SOP combined with SOP ECTU_REDCap_09 Project Lock – Sectional Lock (now withdrawn from use)

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		• Change to document name • Extensive changes to entire document to reflect process more clearly • REDCap Database Total Lock Template reference removed (now withdrawn from use) • New templates RC013 REDCap Study Database Lock Log and RC014 REDCap Study Database Unlock Log reference added

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1.0   PURPOSE

This SOP describes the procedure for managing a database lock or unlock request, including request requirements and documentation of the process.

The procedures used to complete the lock or unlock are further described in ECTU Central Office WPD ECTU_REDCap_W3 Database Lock and Unlock Procedures that is associated with this document.

In cases where more than one database is applicable for the study (for example, main study database and Screening Log database), this procedure applies to each database.

2.0   SCOPE

This SOP applies to staff in the following roles within the ECTU Data Management Team as REDCap study database developers:

- Data Manager
- Assistant Data Manager
- Data Management and Programming Architect

This SOP applies to the Trial Manager or appropriate study designee who oversees the completion of all activities prior to database lock.

This SOP applies to the Trial Statistician or appropriate study designee who request a database lock or unlock.

3.0   RESPONSIBILITIES

The Trial Manager or appropriate study designee is responsible for ensuring all necessary activities have been completed and approvals are in place before the database lock or unlock is requested.

The Trial Statistician or appropriate study designee is responsible for formally requesting a study database lock or unlock. This must be done in writing (for example, via email) to the database developer.

The database developer or designee is responsible for documenting and completing the lock or unlock of the study database as per the procedures described in this SOP and related WPD once a request is received from the appropriate designee. As much as possible the database lock should be completed by the assigned database developer but can be completed by a designee if required.

4.0   PROCEDURE

4.1   Definitions

4.1.1   A **database lock** is when functionality is altered on the database so that the data cannot be amended or added to, by any user after the designated lock date. It may also include removing other functionality that does not directly impact the data such as export rights or read only rights.

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4.1.2 A **full database lock** is when the entire database is locked so that all data in all sections of the database cannot be amended or added to. This is the most common type of lock used prior to final analysis at the end of study. No database design changes or modifications will be made to a fully locked database.

4.1.3 A **partial database lock** is when only specific sections or records of the database are locked so that all data in only these sections or records cannot be amended or added to. All other sections or records will remain open to the appropriate users. Database design changes can still be made to partially locked databases depending on the status of the study and requirements.

4.1.4 A **database unlock** is when the lock is reversed to allow further amendment of the data. An unlock should be limited to only the sections that require amendment where possible. To preserve the data, a full database unlock should be avoided if possible.

4.2 Requesting a study database lock

4.2.1 A database lock should not be requested until all relevant study activities have been completed and all necessary approvals have been obtained. Please refer to each team's individual guidance and procedures for details of requirements prior to database lock:

- Completion of all Data Management activities including all query and missing data resolution and data cleaning
- Completion of all Trial Management activities including site close-out where applicable
- Completion of all Statistics activities including finalised Statistical Analysis Plan
- Completion of all Sponsor and Monitoring activities where applicable

4.2.2 The Trial Manager or appropriate study designee is responsible for ensuring all activities are completed before the request to lock the database is made. They will be responsible for informing the authorised designee when it is appropriate to formally request the database lock

4.2.3 Requests to lock a study database will only be accepted from an appropriate study designee. In most cases, this will be the Trial Statistician or designee for the study. In cases where this is not applicable, another appropriate individual should be identified to make the requests. This may be the Trial Manager or Chief Investigator for example.

4.2.4 Requests will be made formally in writing (via email) to the database developer including the following:

- Study Name/Acronym
- LIVE Database Name (e.g., main study database, Screening Log database)
- Specify whether it is a full database lock or a partial lock
- If a partial lock, specify which sections/instruments and/or records that are to be locked

4.2.5 Upon receipt and acceptance of the request, the database developer will complete template RC013 REDCap Study Database Lock Log.

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4.2.6 The database developer will lock the database as per the appropriate methods described in ECTU Central Office WPD ECTU_REDCap_W3 Database Lock and Unlock Procedures.

4.2.7 The database lock will then be checked and verified by another database developer. Both the database developer and the verifier will sign the Study Database Lock Log once complete.

4.2.8 Once completed, the database developer will notify the requester and any relevant study designees via email that this has been implemented.

4.2.9 The signed Study Database Lock Log will be retained by the database developer in the study-specific location on ECTU the shared drive and will be saved using the following convention:

<<Study Name/Acronym>> Study Database Lock Log DD/MM/YYYY (Date Lock Completed)

A paper copy will be retained in a study specific data management folder.

4.3 **Requesting a study database unlock**

4.3.1 Requests to unlock a study database should be made by the appropriate study designee as specified in section 4.2.1.

4.3.2 Requests will be made formally in writing (via email) to the database developer including the following:

- Study Name/Acronym
- LIVE Database Name (e.g., main study database, Screening Log database)
- Specify the specific features/instruments that are to be unlocked
- Specify the reason for the request

4.3.3 Upon receipt and acceptance of the request, the database developer will complete template RC014 REDCap Study Database Unlock Log.

4.3.4 The database developer will unlock the database as per the appropriate methods described in ECTU Central Office WPD ECTU_REDCap_W3 Database Lock and Unlock Procedures.

4.3.5 The database unlock will then be checked and verified by another database developer. Both the database developer and the verifier will sign the Study Database Unlock Log once complete.

4.3.6 Once completed, the database developer will notify the requester and any relevant study designees via email that this has been implemented.

4.3.7 The signed Study Database Unlock Log will be retained by the database developer in the study-specific location on ECTU the shared drive and will be saved using the following convention:

<<Study Name/Acronym>> Study Database Unlock Log DD/MM/YYYY (Date Unlock Completed)

A paper copy will be retained in a study specific data management folder.

4.3.8 Requests to re-lock the database should be made according to the process described in section 4.2.

4.4   Removal of key database functionality prior to database lock

4.4.1 Once a study has completed the recruitment phase, the ability to add new participant records and/or randomise an existing participant on the database can be removed. This may also be applicable for safety or other reasons as stated in the protocol.

4.4.2 Removal of these functions does not necessitate a full or partial database lock, only the disabling of these functions and instruments. This will be applied to the entire database. Removal of these functions cannot be implemented on a site-by-site basis.

4.4.3 Requests to disable these functions will be accepted from the Trial Manager or appropriate study designee.

4.4.4 Requests will be made formally in writing (via email) to redcap.ectu@ed.ac.uk including the following:

- Study Name/Acronym
- LIVE Database Name
- Specify functions to be removed
- Specify reason for the request

4.4.5 As these requests may occur at any time or in case of emergency (e.g. due a safety concern), the request can be accepted and completed by any database developer in the Data Management team with appropriate administrative rights.

4.4.6 Upon acceptance of the request, this will be documented using RC015 REDCap Study Database Removal of Functionality Log.

4.4.7 Once completed, the removal will be verified by another database developer. Both database developers will sign the Study Database Removal of Functionality Log.

4.4.8 Once completed, the database developer will notify the requester and any relevant study designees of the removal.

4.4.9 The signed Study Database Removal of Functionality Log will be retained by the database developer in the study-specific location on ECTU the shared drive and will be saved using the following convention:

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<<Study Name/Acronym>> Study Database Removal of Functionality Log DD/MM/YYYY (Date Removal Completed)

A paper copy will be retained in a study specific data management folder.

5.0   RELEVANT DOCUMENTS AND REFERENCES

ECTU Website

- ECTU_SOP_OP_20 Requests to Lock and Unlock a Study Database
- ECTU_REDCap_W3 Database Lock and Unlock Procedures

ECTU Templates

- RC013 REDCap Study Database Lock Log
- RC014 REDCap Study Database Unlock Log
- RC015 REDCap Study Database Removal of Functionality

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ECTU REDCap SOP 07 and W3

Final Audit Report   2024-07-17

Created:	2024-07-16 (British Summer Time)
By:	Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAAfZwxRB-tR0cELajB0-UlSG6jODKHZOm5

"ECTU REDCap SOP 07 and W3" History

📄 Document created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
2024-07-16 - 18:00:47 GMT+1- IP address: 192.41.114.230

✉ Document emailed to Lynsey Milne (Lynsey.Milne@ed.ac.uk) for signature
2024-07-16 - 18:06:35 GMT+1

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2024-07-16 - 18:06:35 GMT+1

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2024-07-17 - 07:26:09 GMT+1- IP address: 104.47.11.254

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Signature Date: 2024-07-17 - 07:26:49 GMT+1 - Time Source: server- IP address: 192.41.114.230

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2024-07-17 - 08:03:04 GMT+1- IP address: 104.47.11.254

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Signature Date: 2024-07-17 - 10:28:28 GMT+1 - Time Source: server- IP address: 192.41.114.224

Document e-signed by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Signature Date: 2024-07-17 - 10:44:17 GMT+1 - Time Source: server- IP address: 192.41.114.230

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