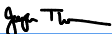# ECTU Central Office SOP ECTU_REDCap_06: Requesting and Implementing a Change to a Study Database

Version No:	3.0
Issue Date:	17 Jul 2024
Effective Date:	14 Aug 2024

Authorship and Approval			
Name and Designation	Author/Reviewer /Approval/ Authorisation	Date	Signature
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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 SOP name as separate naming convention allocated to REDCap SOP/WPDs
3.0	14 Aug 2024	• Document moved to new template • Extensive changes to entire document to reflect process more clearly • Additional Requirements log removed from use for REDCAP studies

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1.0   PURPOSE

This SOP describes the procedure for requesting a change to a live Study Database. This is applicable to all databases that require and change or update after the first initial release to the live environment on the REDCap server.

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 also applies to members of the Trial Management team or appropriate study designee who request changes to the database.

3.0   RESPONSIBILITIES

The Trial Manager or appropriate study designee is responsible for the following:

- Evaluating and authorising the need for a database change
- Requesting the change via the appropriate channels and providing the database developer with the correct information for the required update.
- Testing and validating the changes on the training database before it is released to the live database
- Ensuring the appropriate approvals are in place before a change is released to the live database

The database developer is responsible for the following

- Upon receipt of the change request, liaising with the Trial Manager or appropriate study designee to implement the change as required
- Implementing the change on the training database and preparing all validation documentation
- Ensuring the change is reviewed and approved (where appropriate) by the Trial Statistician or designee and/or Trial Monitor
- Approving all completed validation documents, prior to release to the live database
- Providing completed documentation to the study Sponsor for approval as required
- Upon confirmation of final approval from all relevant parties, releasing the change to the live database

4.0   PROCEDURE

4.1   Requesting a Change to a Study Database

4.1.1   All requests must be logged on the ECTU DM&P Project Change Requests database. The database developer or another REDCap Administrator can provide access to this.

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4.1.2 Instruction on using the ECTU DM&P Project Change Requests database is provided in ECTU Central Office WPD ECTU_REDCap_W2 Requesting a Change to a Study Database.

4.2 Implementing a Change to a Study Database

4.2.1 The database developer will review and accept the change request as appropriate. Database changes can only be made if the database is fully or partially open for current study use. Changes will not be made to any study database that has been fully locked.

4.2.2 The change will be implemented in the training version of the database on the Development server initially in order to be tested and validated.

4.2.3 The changed instruments and functionality will be validated as per ECTU Central Office SOP ECTU_REDCap_04 Study Database Validation.

4.2.4 Once all validation is complete and all approvals are in place, the change can be released on the live version of the database on the Production server. The release procedure is detailed in ECTU Central Office WPD ECTU_REDCap_W1 Database Release Procedure.

4.2.5 Once the database has been released, the database developer will update the status of the request in the ECTU DM&P Project Change Requests database.

5.0 RELEVANT DOCUMENTS AND REFERENCES

ECTU Website

- ECTU Central Office WPD ECTU_REDCap_W2 Requesting a Change to a Study Database
- ECTU Central Office SOP ECTU_REDCap_04 Study Database Validation
- ECTU Central Office WPD ECTU_REDCap_W1 Database Release Procedure

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ECTU REDCAP_03, 04, 06 and W2

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:	CBJCHBCAABAASnICTDa9-u0V6lKXuqElypRhrpMZwfYy

"ECTU REDCAP_03, 04, 06 and W2" History

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2024-07-16 - 17:41:06 GMT+1- IP address: 192.41.114.230

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2024-07-16 - 17:50:03 GMT+1

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